DMM

DRUG MANAGEMENT FOR MALARIA MANUAL

Malcolm Clark

June 2000

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Rational Pharmaceutical Management Program
USAID Cooperative Agreement Number:
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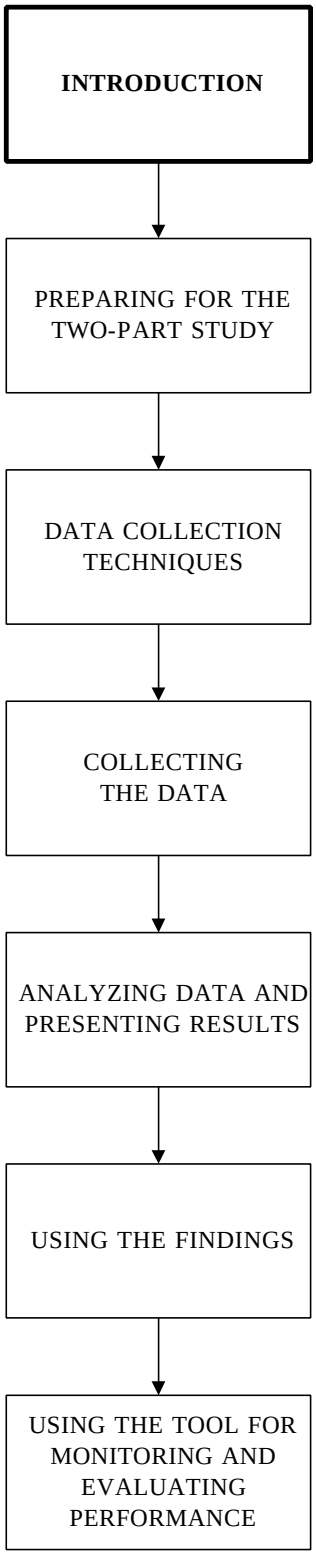
ACRONYMS

BASICS..... Basic Support for Institutionalizing Child Survival
CDC .....U.S. Centers for Disease Control and Prevention
CIF ..... cost, insurance, and freight
CMS .....Central Medical Stores
DAS.....Drug Availability Study
DMM..... Drug Management for Malaria
DUS.....Drug Use Study
EDL.....Essential Drugs List
FOB..... free on board
HIV .....human immunodeficiency virus
IDA ..... International Dispensary Association
INRUD.....International Network for Rational Use of Drugs
LA/C .....Latin American/Caribbean
MOH .....Ministry of Health
MSH..... Management Sciences for Health
NDF.....National Drug Formulary
NGO.....nongovernmental organization
OTC.....over the counter
PAHO..... Pan American Health Organization
RBM.....Roll Back Malaria
RMS .....Regional Medical Stores
RPM ..... Rational Pharmaceutical Management [Project]
STG..... Standard Treatment Guideline
SP .....sulphadoxine pyrimethamine
USAID ..... U.S. Agency for International Development
VEN .....vital, essential, nonessential
WHO.....World Health Organization

DRUG MANAGEMENT FOR MALARIA MANUAL



Chapter 1.

INTRODUCTION

Background

In 1997, malaria risk of varying degrees existed in 100 countries and territories. In 92 of these, transmission included the malignant (*Plasmodium falciparum*) form of the disease. Over 40 percent of the world population lived in areas with malaria risk. Every year there are between 300 million and 500 million new cases of malaria, which result in 1.5 million to 2.7 million deaths annually. Approximately one million of these deaths are among children under five years of age, mainly in Africa. Overall, countries in tropical Africa account for more than 90 percent of the total malaria incidence and the great majority of malaria deaths. The economic loss due to malaria in Africa in 1989 was estimated at $800 million. By 1997 this figure had risen to $2 billion, an enormous burden to an already poor continent.

The burden of malaria has been intensified by the appearance of chloroquine-resistant *Plasmodium falciparum*, which arose in southeast Asia and was first documented in East Africa in 1979. Since then, there have been reports of chloroquine resistance in most countries in Africa

with especially high resistance in East Africa.[1] In addition, resistance to sulfadoxine-pyrimethamine (SP) is increasing.[2]

Evidence is also growing to show the relationship between increased resistance to first-line antimalarial therapy and increased morbidity and mortality.[3] Resistance has also been implicated in the increasing frequency and severity of epidemics.

The growing threat from malaria[4] as a result of the development of resistance has prompted a number of African countries to change or reconsider their malaria drug policies. Malawi, Kenya, Botswana, and South Africa have already adopted SP as their first-line antimalarial drug while Tanzania changed its policy in early 2000. Combination therapies are also being increasingly considered as a strategy for overcoming the problem of resistance. It was also against this background that the World Health Organization (WHO) launched its global Roll Back Malaria (RBM) initiative in October 1998. RBM has set the objective for itself of halving the malaria burden in participating countries by 2010.

A key part of any strategy to Roll Back Malaria is to have effective and affordable drugs widely available and to use them in a way that will delay the emergence of resistance. WHO/RBM has therefore identified improving the supply and management of antimalarial drugs as a critical part of any strategy for "rolling back malaria."

To address issues of the essential drugs needed for treating malaria, the Rational Pharmaceutical Management (RPM) project, in collaboration with the U.S. Agency for International Development (USAID), developed the *Drug Management for Malaria (DMM) Manual*, an indicator-based assessment tool. The *DMM Manual* is designed to guide the review of drug availability and rational use of drugs for malaria treatment in drug retail outlets and in the health facilities of the Ministry of Health (MOH). Such reviews will help to provide the evidence required for making decisions on how to improve access to, as well as the use of, antimalarial drugs in both the public and private sectors.

[1]Chloroquine treatment failure at 25mg per kg of body weight in Tanzania, for example, is 52%. (Report of the Tanzania MOH, Task Force on Antimalarial Drug Policy, July 23, 1999).

[2]In Tanzania, SP treatment failure is 9.5% (Tanzania MOH Task Force report, July 23, 1999).

[3] See (1) J.F. Trape, et al., 1998. Impact of chloroquine resistance on malaria mortality. *Comptes Rendus de l'Academie des Sciences* Serie III; 321(8): 689–97, (2) K. Marsh, Malaria disaster in Africa. *Lancet* 352: 924–25.

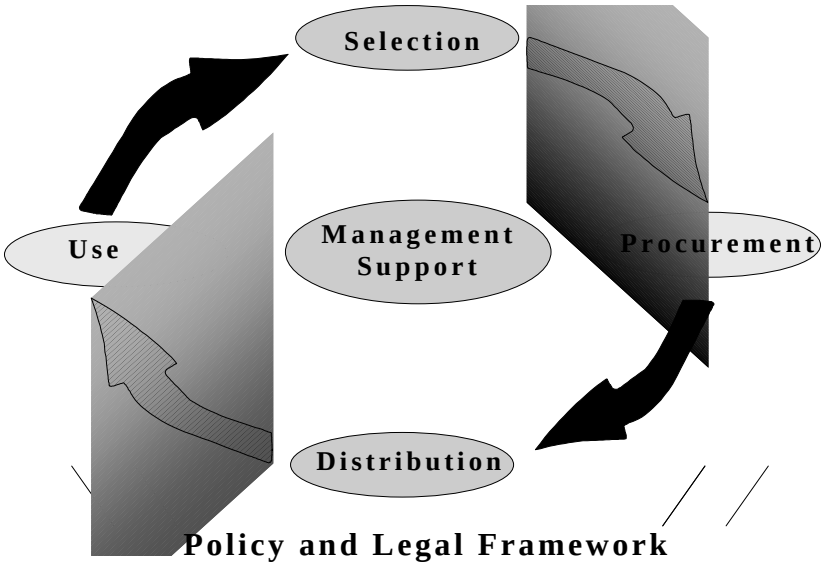
[4] N.J. White et al., 1999. Averting a malaria disaster. *Lancet* 353(9168): 1965–67.

Cornerstones of Drug Management: Selection, Procurement, Distribution, and Use

Drug management involves four basic functions: selection, procurement, distribution, and use. Selection involves reviewing the prevalent health problems, identifying treatments of choice, choosing individual drugs and dosage forms, and deciding which drugs will be available at each level of health care. Procurement includes quantifying drug requirements, selecting procurement methods, managing tenders, establishing contract terms, assuring drug quality, and ensuring adherence to contract terms. Distribution includes the clearing of customs, stock control, stores management, and delivery to drug depots and health facilities. Use includes diagnosing, prescribing, dispensing, and proper consumption by the patient. Each function builds on the next, forming the drug management cycle.

At the center of the drug management cycle is a core of management support systems: organization, financing and sustainability, information management, and human resources management. These management support systems hold the drug management cycle together. Finally, the entire cycle rests on a policy and legal framework that establishes and supports the public commitment to essential drug supply. Figure 1 shows a graphic display of the drug management cycle.

Figure 1. The Drug Management Cycle



As described in Chapter 2, this manual uses a two-part study to review different areas of the drug management cycle. The Drug Availability Study (DAS) looks at various aspects of selection, procurement, and distribution. The Drug Use Study (DUS) analyzes the use of drugs for malaria by reviewing the prescribing practices of health workers in MOH facilities and drug retail outlets, the quality of the dispensing practices, and the quality of the drug information provided to consumers in these two settings.

Drug Management in Support of Malaria Programs

One barrier to effective case management of malaria in the health system is that the drugs needed are often not available. The effective prevention and treatment of malaria requires that health workers and consumers have access to a core group of drugs and supplies. If these products are not available, effective treatment cannot be given.

The actual management and use of pharmaceuticals is influenced by a wide range of factors, including drug availability, provider experience, economic influences, cultural factors, community belief systems, and the complex interactions among these factors. Drugs have special importance for the following reasons:

- Drugs save lives and improve health.
- Drugs promote trust and participation in health services.
- Drugs are costly.
- Significant improvements in the supply and use of drugs are often feasible.

Lack of careful selection, incorrect quantification, high prices, poor quality, theft, improper storage, expiration of drugs, irrational prescribing, and incorrect drug use by patients result in losses that can total more than 70 percent of initial acquisition costs. Improving the supply and management of essential drugs and supplies needed for malaria is possible. Effective management saves money and improves care by increasing drug availability and promoting rational drug use.

The drugs that providers prescribe and dispense are an important index of the quality of care they deliver. The capacity to analyze prescribing data efficiently and make quantitative summaries of prevailing practices is one key to evaluating quality of care and intervening to improve care delivery.

Purpose of the Assessment and Target Audience

Purpose of the Assessment

Country-level preparation activities for improving malaria interventions should ensure that the drugs recommended in the adapted treatment guidelines are available. Accomplishing this task requires a thorough assessment. This *DMM Manual* presents an indicator-based approach for assessing pharmaceutical management systems (both public and private sector) and programs specifically tailored to the needs of malaria. This *DMM Manual* has a number of potential applications, including—

- Defining the status of the pharmaceutical system, including strengths and weaknesses, for managers and donors
- Designing and planning interventions
- Defining budget or resource requirements

- Monitoring changes in systems and the impact of interventions
- Comparing the performance of different systems, programs, or countries

Completion of the assessment should result in the identification of problems, which problems might be solved, and what types of interventions are practical in terms of cost-effectiveness and feasibility.

Target Audience

This manual is intended for use by health professionals with a background in drug management and who work at the central, regional, and/or district level. The users of this manual may include the following:

- WHO and the Pan American Health Organization (PAHO) Essential Drugs Program staff in Latin America and the Caribbean (LA/C), Africa, and Asia
- Ministry of Health decision makers, health planners, health economists, donor representatives, or experts responsible for malaria activities;
- System managers at the national, regional, or local levels wishing to measure the performance of the malaria drug management and supply system
- Social scientists and health project or facility managers who are interested in malaria operational research and management tools

Objectives

The purpose of the *DMM Manual* is to assist the user in assessing those aspects of the drug management system that are critical to ensure the availability and proper use of drugs and supplies essential to preventing and treating malaria. **This manual is not intended for users who need or wish to conduct a complete assessment of the entire pharmaceutical system.** Such an assessment is beyond the scope of this manual. RPM has developed the *Rapid Pharmaceutical Management Assessment: An Indicator-Based Approach* manual to serve as a guide for conducting a complete assessment. The *DMM Manual*, while based on the rapid assessment model, is tailored to preventing and treating malaria and complements the more general manual.

The main objective of this manual is to provide an approach for conducting studies that will—

- Provide data on availability and prescribing practices of drugs used for preventing and treating malaria
- Identify ways to improve malaria drug management (availability, treatment, and cost)
- Transfer self-assessment technology by creating country-based operations research capacity

How to Use the DMM Tool

The DMM tool consists of two components: this manual for the lead investigator(s) and a companion *DMM Data Collector's Guide* to assist with data collection and analysis in the field. There are also diskettes containing a set of the generic DMM data collection forms to facilitate country-specific adaptation and printing. It is important for study organizers to thoroughly review the *Data Collector's Guide* before training data collectors and beginning the studies.

The *DMM Manual* is designed to take users step-by-step through the malaria drug management process, beginning with introducing the concept of indicator-based assessments, then conducting studies that identify specific strengths and weaknesses of the drug supply system for malaria, and ending with recommendations for ongoing performance monitoring and possible strategies for improvement. The assessment is built around two complementary studies: Drug Availability Study (DAS) and Drug Use Study (DUS). The two studies assess various aspects of drug management in the public and private sectors.

The Drug Availability Study (DAS): The purpose of conducting the DAS is to determine the degree to which the antimalarial drugs required for treating and preventing malaria are available. The DAS indicators will help the investigators to identify possible reasons for the low availability of antimalarial drugs, as well as opportunities for improving the supply. These indicators will guide efforts to ensure that the drugs required for malaria are available. Three data collection techniques will be used: document reviews, structured interviews, and physical inventory checks.

The Drug Use Study (DUS): The purpose of the DUS is to review prescribing and dispensing practices for malaria and assess their clinical and cost implications. This information will be used to involve prescribers in the initiative and to target specific behaviors to encourage or discourage through training and subsequent monitoring and supervisory activities. The DUS will use both retrospective and prospective methods. For the retrospective component of the study (in MOH facilities only), the data collection technique used will be medical records review. The prospective component will use the techniques of direct observation, simulated patient and exit poll interviews in MOH facilities, and simulated purchases in drug retail outlets. The data collection techniques used in the availability and drug use studies are described in Chapter 3.

Each study uses specific indicators to measure the performance of a particular aspect of the malaria drug supply system. Objective indicators and specific program targets provide concrete measures against which actual performance can be compared. There are four general criteria for useful indicators. These are—

- Importance - Each indicator must reflect an important dimension of performance.
- Measurability - Indicators must be measurable, within constraints of time, variable quality, and availability of data.
- Reliability - Each indicator must be reliable over time and with different observers.

- Validity - Each indicator must allow a clear and consistent interpretation and have a similar meaning across different environments.

The indicators used in each of the two studies described below meet these basic criteria.

List of DMM Indicators

Following is the list of 13 DMM indicators that will be used to assess the availability and use of antimalarial drugs for the treatment of malaria. The list includes four availability indicators, seven drug use indicators, one observation indicator, and one supplemental indicator. The detailed text for the DMM indicators is included in Annex 1. Annex 2 presents a sample format for presenting the indicator data.

Drug Availability Study Indicators

1. Percentage of median international price paid for a set of DMM antimalarial drugs that were part of the last regular MOH procurement

2. Average percentage of a set of unexpired DMM antimalarial drugs available in (a) MOH storage and health facilities and (b) retail drug outlets

3. Average percentage of time out of stock for a set of DMM antimalarial drugs in MOH storage and health facilities

4. Average percentage of stock records that correspond with physical counts for a set of DMM antimalarial drugs in MOH storage and health facilities

Drug Use Study Indicators

5. Percentage of MOH health facilities visited with a copy of official treatment guidelines for malaria

6. Percentage of encounters with patients diagnosed with uncomplicated malaria that are prescribed an antimalarial consistent with treatment guidelines

7. Percentage of encounters with patients diagnosed with uncomplicated malaria that are prescribed quantities of appropriate antimalarials sufficient to complete a full course of treatment

8. Percentage of prescribed antimalarial drugs actually dispensed by public health facilities

9. Percentage of cases where the quantity of antimalarial drugs dispensed by public health facilities was sufficient to complete a course of treatment

10. Average cost of drugs prescribed as a percentage of costs if Standard Treatment Guideline (STG) norms for treatment were followed

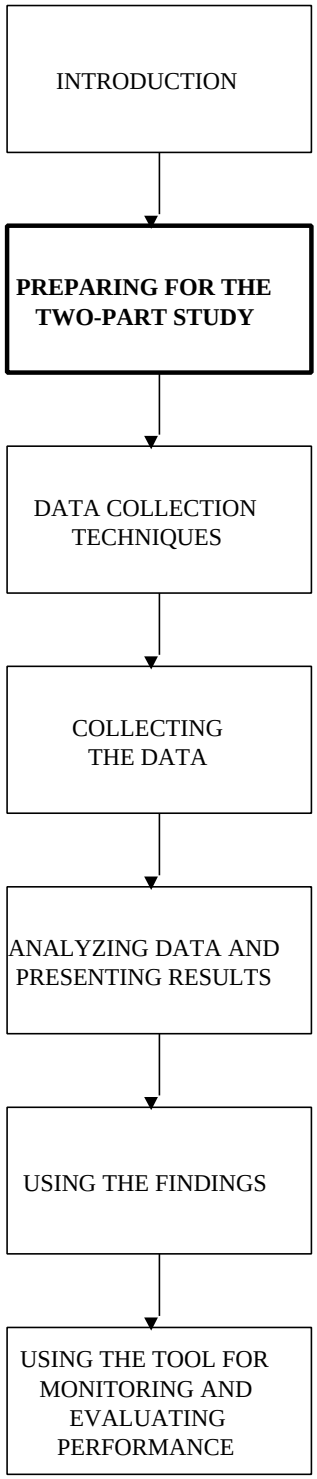
11. Percentage of patients/caregivers who could correctly describe how to give the prescribed antimalarial medication

12. Percentage of health workers and drug retail outlets that provided [some] information to patients/caregivers on how to give the recommended drug(s)

Supplemental Indicator

13. Percentage of encounters with pregnant women living in endemic areas that are prescribed appropriate antimalarial prophylaxis at antenatal clinics

DRUG MANAGEMENT FOR MALARIA MANUAL



Chapter 2.

PREPARING FOR THE TWO-PART STUDY

This manual is intended as a tool to assess the drug management system in support of malaria programs. The DMM tool is an indicator-based, two-part study. Although the investigators may decide to conduct only one part of the study, the general approach to a systematic assessment requires answers to the following questions:

Availability

1. Are the drugs that are required to prevent and treat malaria available in public health facilities?

2. What are the determinants of antimalarial drug availability in the public sector and what can be done to bring about improvement?

Use

1. What are current prescribing practices for malaria?

2. Are the current prescribing practices clinically appropriate?

3. How does the drug cost of current practices for treating malaria compare to what the cost would be if malaria treatment guidelines were followed?

4. Are drugs that are required to prevent and treat malaria available and affordable in the private sector?

As part of the preparation to conduct the studies, two tasks must be completed: gathering background information and preparing an overview of the MOH drug management operations. This information will be useful in training data collectors and in putting the findings in the proper context.

Gathering Background Information

As mentioned earlier, certain figures, rates, and malaria statistics are important to the study of malaria drug management. Investigators should collect and record the following data, shown in Table 1, at the very outset of the work and before the start of data collection.

Table 1. Background Information

Background Information
Prevalence and incidence of malaria[1]
Prevalence and incidence of drug resistance[1]
Existence of Standard Treatment Guidelines for Malaria
Dates covered by the government fiscal year
Exchange rates of local currency for US dollars for the data collection periods
Inflation rates for the previous five years
National and regional population figures
Rates of population increase

[1] Include date of survey, geographic region(s), and age group(s) covered.

Preparing an Overview of MOH Pharmaceutical Management Operations

To efficiently carry out the two-part study, including interpreting the results and making recommendations for supply system improvement, it is essential to have a good understanding of current drug management operations. At a minimum, this knowledge should include qualitative descriptions of major problems that affect the movement of drugs through the procurement and distribution system and the information listed in Table 2.

Table 2. MOH Pharmaceutical Management Operations

MOH Pharmaceutical Management Operations
Numbers and distribution of MOH health facilities, pharmacies, and warehouses
Numbers and distribution of drug retail outlets
Numbers and distribution of drug wholesalers, distributors, and manufacturers
Diagram showing system of drug procurement and distribution for malaria drugs. The diagram should also include the offices responsible for managing procurement of malaria products (by both purchase and donation), storage facilities, and health facilities.
List of sources of malaria drugs flowing through the distribution system and estimated values for each source, including budgets, and contributions of donors and nongovernmental organizations (NGOs)
Summary of transport arrangements linking storage and health facilities. This should be as specific as possible, indicating numbers and types of vehicles available by geographic zone. If transport is through contract arrangements with parastatal or commercial agencies, describe those arrangements and indicate the budgets.
Copy of National Drug Formulary/Essential Drugs List (NDF/EDL) or total number of malaria drug products plus total number of all drug products on the list
Copy of any recent or proposed changes made to antimalarial drug policy not reflected in NDF/EDL
Is there a system(s) for recovering the cost of drugs dispensed in MOH health facilities? Identify the system(s).

In most countries, investigators will gather all of these items through interviews and document review. The best approach is to prepare a plan for collecting this information (see Table 3).

Table 3. Plan for Collecting Information to Provide an Overview of Drug Management Operations

Information Required	Whom to Ask/Interview	What Document to Review or Data to Collect
Organigram	Central Health Administration, Pharmaceutical Section	Organizational structure of health system including job titles and names of persons
Drug sources	Central Warehouse Administration	Invoices of drug orders and receipts
Central/District budgets	Central and District Health Administrative Offices	Budgets for last two years plus current year
Warehouse distribution	Central/Regional Warehouse Administration	Distribution plan: list of pharmacies and health centers indicating flow of drugs
Transport arrangements	Central/Regional Warehouse Administration	Transportation schedule for all pharmacies and health centers, indicating how drugs are delivered
Major procurement problems	Central/Regional Warehouse and Pharmaceutical Section of Central Health Administration	Reports of past tenders, drug orders, and receipts; interviews with section director and warehouse director
Major distribution problems	Central/Regional Warehouse and Pharmaceutical Section of Central Health Administration	Reports of distribution problems; interviews with section director and warehouse director

Planning the Study

The two-part study collects data from four different settings: central level (C), regional level (R), health facilities (F), and drug retail outlets (D). Each part addresses some aspect of the questions listed at the beginning of this chapter and, when viewed together, they provide a comprehensive assessment of the malaria drug management situation.

Selection of Personnel to Conduct the Assessment

RPM's experience in conducting a country-wide assessment of the drug management system suggests that the most practical way to carry out this type of study is for two or more experienced investigators to work together over a period of four to six weeks. An ideal combination would include the following:

- A *pharmaceutical management specialist* to take charge of study coordination and data collection for logistics at the *central and regional* levels. For this job, familiarity with pharmaceutical policy, logistics management, procurement, and budget issues would be most useful.

- A *health care provider* such as a physician, pharmacist, or nurse to take charge of the surveys to be carried out at the *health facility and retail outlet* levels. For this job, familiarity with pharmaceutical products and work routines in health facilities would be an asset.

- The work of the investigators is supplemented by a team of data collectors who visit medical stores, health facilities, and drug retail outlets.

Selection of Target Sites

The data collection takes place at the central level, central and regional medical stores, health facilities, and retail outlets. Table 4 provides a list of data collection sites that should be included in conducting both studies.

Table 4. Data Collection Sites for Each Part of the Assessment

Study	Data Collection Sites
Drug Availability Study	Ministry of Health Central Office
	Ministry of Health/Central Medical Store
	Regional Medical Stores
	Health Facilities (hospitals and primary health care facilities)
Drug Use Study	Health Facilities (hospitals and primary health care facilities)
	Drug Retail Outlets

Conducting an assessment in all of these sites may look difficult, but, in practice, the entire set of 13 DMM indicators can be sorted into two groups, which constitute two distinct data collection efforts:

- At the *central and regional levels*, data are collected for four availability indicators, of which two are collected through structured interviews and document review, and two through physical inventory and stock record review at the central and regional medical stores and health facilities.

- At the *health facility and retail outlet levels*, data for three DAS indicators and nine DUS indicators are collected through sample surveys. The health facility data collection effort requires organizing a survey to collect different types of data in 20 sites. The survey includes physical inventory and stock record review, patient record reviews, direct observations, exit poll interviews, simulated patient and simulated purchases. Similarly, a sample of 20 drug retail outlets is surveyed through interviews and simulated purchases.

After completing the two preparatory tasks previously discussed, the next activity is to **plan the study** and to **develop a preliminary budget**. The financial and human resource requirements may be reduced if only one part of the study is carried out at a time. However, in general, it is more cost-efficient to consolidate the data collection for the two studies into one overall process. Therefore, this manual will provide guidance for planning and carrying out both studies. The study plan consists of three steps:

1. Appoint investigators and assign responsibilities.
2. Plan data collection.
3. Develop the sample design.

Step 1: Appoint Investigators and Assign Responsibilities

The investigators will spend about one week planning the study, two to three weeks in data collection, and two to three weeks analyzing data and writing the report. The basic organizational strategy is to approach the assessment as two separate data collection efforts:

- Collection of data at central and regional level
- Sample survey of health facilities and drug retail outlets

As described earlier in the section titled Selection of Personnel to Conduct the Assessment, each of the two investigators should be in charge of one of the data collection efforts. Specifically, the *pharmaceutical management specialist* should be in charge of organizing the collection of central and regional data and the *health care provider* should be in charge of the surveys of health facilities and drug retail outlets. Actual data collection may be largely or entirely handled by a team of data collectors.

Each of the investigators should be responsible for carrying out the preparatory steps for their respective data collection areas, as described earlier in this chapter. Another important planning assignment is preparation of a budget for the assessment. This should be a collaborative effort and, at a minimum, involve both investigators. The budget should include a detailed listing of the costs to be incurred, such as the following:

- Salaries of investigators and data collectors
- Preparation and reproduction of data collection forms
- Communications with district and local authorities
- Training of data collectors
- Travel and per diem for the investigators
- Travel and per diem for data collectors
- Data entry costs
- Other costs during the study

Step 2: Plan Data Collection

All of the data required at the central level should be available in the capital city, and most of it should be obtainable through structured interviews and document review. Most of the vital statistics and background information in Tables 1 and 2 of this chapter will be collected at the central level. Data collection at the levels of the health facilities and drug retail outlets will require a visit to each health facility and drug retail outlet included in the sample.

Two types of data collection instruments are required for carrying out the studies described in this manual. One is central and regional level data collection checklists and questionnaires and the other is data collection forms for health facilities and drug retail outlets. Sample checklists, questionnaires, and forms are listed in Table 5 and are presented in the *Data Collector's Guide*.

Table 5. Summary of Data Collection Instruments Required by Each Study

Drug Availability Study
DAS-1: General Data Collection Preparation Checklist
DAS-2 A-E: Inventory Data Form
DAS-3 A-D: Stock-Out Data Form
DAS-4: International Price Comparison Form
Drug Use Study
DUS-1: Medical Records and Facilities Resources Review Form
DUS-2: Observation of Health Workers Data Form
DUS-3: Exit Poll Interview Form
DUS-4: Simulated Purchase Data Form
DUS-5: Simulated Patient Data Form

Step 3: Develop the Sample Design

Developing the sample design is discussed in detail in this chapter under the section "Selecting Data Collection Sites."

Adapting the Tool

To adapt and test the data collection instruments, follow these procedures:

- **First**, one of the investigators should review the sample data collection instruments and identify any terms, references, or questions that are not applicable to the country-specific setting. For example, some countries may use the terms *central*, *regional*, *district*, and

community to describe the levels of MOH facilities, while others may use the terms *national*, *provincial*, and *local* for MOH levels. Similarly, local names for malaria should be researched and included. The suggested changes should then be reviewed by the other investigator (or other study team members) and a consensus reached on the needed changes. Where necessary, add the list of DMM antimalarial drugs.

- **Second**, visit a few health facilities and test the data collection instruments and the methods for collecting the data as described in this chapter. Relevant cost data should be collected to assist with budget planning. For example, drug cost information would help prepare a budget for purchasing drugs during simulated purchase exercises.

- **Third**, revise the data collection instruments and, if necessary, the data collection methodology to ensure familiarity with the entire data collection process and confirm readiness to train data collectors to do their job.

N REMEMBER

It is essential to understand that all of these are sample forms, and although they have been used in a number of countries, they still must be tested and adapted prior to launching data collection activities.

Preparing the List of DMM Antimalarial Drugs

Some of the indicators are measured on the basis of a list of selected antimalarial drugs. There is no "universal" antimalarial drug list. The DMM antimalarial drug list will be used at the central, regional, health facility, and retail levels to collect data for deriving inventory management and price indicators. The DMM drug list in Table 6 is a sample antimalarial drug list. The sample DMM antimalarial drug list should be adapted to the country-specific setting taking into account recent drug policy changes.

It is important to note that the malaria drug supply system should not be a separate supply system. Since the drugs for malaria are essential to public health care in most developing countries, they should be integrated into the national drug supply system to avoid duplication.

To prepare a DMM antimalarial drug list, gather a group of local malaria experts to review the sample list and prepare a list of commonly used antimalarial drugs that should be available in the stores and at each level of MOH health facilities.

N REMEMBER

This sample DMM antimalarial drug list must be adapted and finalized in terms of local products used, dosage forms, and strengths before using it in the studies.

Presented in Table 6 is a sample list of drugs that can be used as an antimalarial list. The list is meant only as an example. For some of the drugs presented in the sample antimalarial list, more than one strength and/or formulation of the drug is presented. For example, chloroquine 150mg tablets and chloroquine 50mg/5ml syrup are included. When adapting the DMM antimalarial drug list, and for preparation of the data collection forms, only one unique formulation (the one most readily available) should be selected. If more than one strength and/or dosage form of a drug is included on the antimalarial list, each one should be listed as a separate drug on the data collection form to ensure accuracy of the data.

Data collection forms DAS-2, DAS-3, and DAS-4 use the DMM antimalarial list. The sample data collection forms list only one form (strength and dosage form) of a particular drug per line. Once the antimalarial list adaptation process is complete, the data collection forms should be revised to reflect the adapted, country-specific DMM antimalarial drug list.

Table 6. Sample List of DMM Antimalarial Drugs

1. Chloroquine phosphate 150mg tablet
2a. Chloroquine injection 40mg/ml 30ml vial
2b. Chloroquine injection 40mg/ml 5ml vial
3. Chloroquine syrup 50mg/5ml
4. Sulphadoxine-pyrimathemine (Fansidar) 500mg/25mg
5. Amodiaquine
6. Quinine 300mg tablet
7. Quinine 300mg/ml injection
8. Sulphametopyrazine + pyrimethamine (Metakelfin) 500mg/25mg tablet

Where there are different sizes of the same drug presentation, chloroquine injection in this example, they should be treated as variations of a single item. Hence chloroquine injection in 30ml and 5ml vials is listed as 2a and 2b. In assessing availability, they would be treated as a single item. For example, chloroquine injection 40mg/ml would be considered available if the 30ml vial was available while the 5ml vial was out of stock.

Selecting Data Collection Sites

Sampling

The goal of the sampling process is to collect enough data, in terms of the actual number of patient encounters and variety and number of sites, for the results to be considered representative of current malaria drug availability and use within the country. This aspect of the planning process is very important and deserves careful consideration by organizers of the assessment. Failure to ensure that the data set collected is a large enough and varied enough sample to be

considered representative could seriously limit the utility of the data analysis and conclusions, because the findings will not be generally representative of the country's malaria drug management situation. The following sections address the four areas of sampling that are critical to the malaria drug management assessment process.

To understand the approach for the study design proposed in this manual, it is important to review the purpose and intent of the malaria drug management assessment. To summarize:

- The purpose of the assessment is to identify high-priority problem areas that might hinder the implementation of malaria program objectives and to point to appropriate follow-up activities.

- The study design is cross-sectional to establish the baseline for monitoring of future interventions.
- The study design is not intended to compare regions, districts, or facilities but rather to describe a reasonably representative drug management profile for the sample as a whole.

- The study design is intended to facilitate the logistics of the data collection effort within a reasonably short time (one day per health facility) and with limited financial resources.

The next step in the design process is the selection of patient encounters and the selection of health facilities and drug retail outlets.

N REMEMBER

This survey design task is divided into four steps:

1. **Selection of the central and regional sites sample**
2. **Selection of the health facilities sample**
3. **Selection of the patient encounter sample**
4. **Selection of the drug retail outlet sample**

Step 1: Selection of Central and Regional Sites Sample

The exercise of constructing the overview of MOH pharmaceutical management operations often reveals that important variations exist within a procurement and distribution system, and that those differences may affect the supply of antimalarial drugs. Some features of the system vary from region to region, from facility to facility, and from prescriber to prescriber. These local variations include such items as climate, financing, sources of drug supply, ease of access to facilities, condition of inventory records, or patterns of prescribing practices.

It is important to include facilities representing all significant variants of the overall system in the sample. One way to do this is to choose four geographic areas (that is, districts or regions) in which to work, based on an informed division of the country into groupings determined by such variables as geography, socioeconomic factors, population density, or key features of the health care system. Below are some criteria for selecting four areas in a country.

- The capital city and the main population center (if different) should always be included as one or two of the study areas.

- If the country is relatively homogeneous, geographically and epidemiologically, simply choose the capital city and three other regions or districts at random.

- If you expect varying conditions in different areas of the country to influence the way pharmaceuticals are managed (e.g., malaria endemic and nonendemic areas), first organize all regions or districts into groups, based on these characteristics; then select the capital city and three study areas at random from these groups.

The following three examples show how geographic considerations may be used to develop a sample that is representative of the country:

Example 1: (1) Capital city; (2) Highland agricultural district; (3) Lowland agricultural district; and (4) Arid district

Example 2: (1 and 2) Capital city and one other densely settled urban area; and (3 and 4) Two rural agricultural districts

Example 3: (1) Capital city; (2 and 3) Two rural districts with reasonably good transportation links; and (4) One relatively inaccessible rural district

Step 2: Selection of the Health Facilities Sample

The sample size used in this manual is 20 health facilities, 5 from each of the four selected geographic regions of the country. The rationale for selecting a sample size of 20 health facilities is based on experience and the study design factors and assumptions previously discussed.

To make the actual site selections, follow these procedures:

- First, select the district hospital outpatient unit, which should always be one of the facilities selected in each study district. Select randomly[5] if there is more than one district hospital in the district.

[5] Random selection is a range of techniques used to eliminate bias from the process of choosing units to be included in a study. These techniques are designed to give every unit in a particular set an equal opportunity of being selected.

- Then, randomly select four other health facilities from the list of health centers in the selected district. For systems organized with only one basic tier of outpatient facilities below the district hospital (for example, rural health centers), select the other four as follows:

- If geographic distances and transportation logistics are such that all facilities can be visited and all data can be collected in one day, select four of these second-level units at random, from all of those in the district.

- If transportation is more difficult, select two facilities at random, and then choose two other facilities that are geographically close to them, so that the paired facilities may be visited in one trip.
- For systems with two tiers below the district hospital level (for example, polyclinics staffed by physicians and lower level health posts staffed by paramedics), select the other four facilities as follows:

  — Choose two second-level health facilities at random.

  — For each of those two second-level health facilities, choose, from among the group of third level-facilities that are geographically close, one site. The result is paired sets of second- and third-tier facilities.

- For systems that are organized in a different way, distribute the five facilities to be studied in each district among the possible types of health facilities, according to such factors as their geographic location or patient load.

Step 3: Selection of the Patient Encounter Sample

The sample of patient encounters is important for the Drug Use Study. A minimum of 600 patient encounter records must be reviewed for each categorization of malaria. This number is achieved by randomly selecting 30 medical records for malaria in each of the 20 health facilities. Examples of patient encounter records include daily registers, medical records, or prescription slips. The rationale for selecting a sample size of 600 malaria patient encounters is that experience has shown that the results of collecting larger samples are not more useful for identifying the main problems, and therefore, do not justify the increased time, cost, and effort.

For the main Drug Use Study indicators, uncomplicated malaria alone is included for study. However, a supplemental indicator (13) dealing with chemoprophylaxis given to pregnant women as presumptive treatment during antenatal care is included for use in countries where this form of treatment is in line with government policy. In a country with such a policy, therefore, 600 malaria patient encounter records are needed for uncomplicated malaria (30 randomly selected per facility) and a further 600 antenatal records would be needed. A total of 1,200 patient encounters would therefore be required if indicator 13 is included in the study.

N REMEMBER

The most important principle to remember in each phase of this process is *random selection*.

The simplest approach to random selection is to apply the interval method to site lists. Make sure that the site lists are complete and organized alphabetically, and select every n^{th} site, where n is determined by dividing the total number of available sites by the desired sample size. For example, if there are 40 sites available, and four are needed for the study, select every 10^{th} site ($n = 10$) on the list.

Step 4: Selection of the Drug Retail Outlet Sample

The sample size for drug retail outlets is 20, five from each of the four geographical regions of the country. The most commonly recognized drug retail outlets are pharmacies. However, there may be other types, such as over-the-counter (OTC) drug stores. It is important to obtain a clear idea of the different types of outlets operating, their relative proportions and geographic distributions, and regulations that affect what may be sold. The drug retail outlet sample should be selected to include proportional numbers of all major types. To do this, apply the principles described above for sampling different types of health facilities.

In selecting the drug retail outlet site sample, the simplest approach, from the logistical point of view, would be to choose the site that is geographically closest to each randomly selected health facility visited. Two problems with this approach are that (a) those outlets situated closest to health facilities may not be representative of all outlets; and (b) in some settings where rural health facilities are located, there may be no pharmacies or other drug retail outlets. A better approach, from the point of view of representative sampling, is random selection within each of the four geographic areas in the sample design. The best way to accomplish this is to apply the systematic interval sampling method to site lists, as described earlier under *Step 2: Selection of the Health Facilities Sample*.

Arranging Logistics

Scheduling

Scheduling is a complicated issue that is affected by factors such as the average time required to collect data in each site, the number of data collectors available, distances between sites, and transport arrangements. It is best to begin by thinking in terms of averages and then make refinements by considering the geographic implications of the site sample of the study. Experience with the indicator studies completed so far suggests that, on average, about one day of data collection time and one to two days of travel time are required for completing work at one health facility.

This experience suggests that 12 data collectors, working in teams of three in the four sites, would require 10 work days each, or perhaps 11 to 12 calendar days for the whole group to travel out, complete work, and travel back. The time required for covering the drug retail outlets must also be considered. For this group of sites, however, work time is much shorter, so the main variable is geographic distribution.

Staffing

Thus far, discussions have covered the roles of the study investigators and the data collectors. Other types of staffing that may be required include one or more data collection managers to supervise and coordinate groups of data collectors, persons to enter or process collected data, and drivers. It should be clear that the practical problems of managing a data collection schedule will be greatly simplified by employing these types of workers. Not employing them to save money will be false economy in most cases.

Transport

It is certainly faster to chauffeur data collectors directly to sites, but buses or other public transport can also be used. In some cases, combination approaches will be useful, in which some data collectors working in closely grouped sites are ferried around by drivers, while others, who are going to remote sites, take the bus.

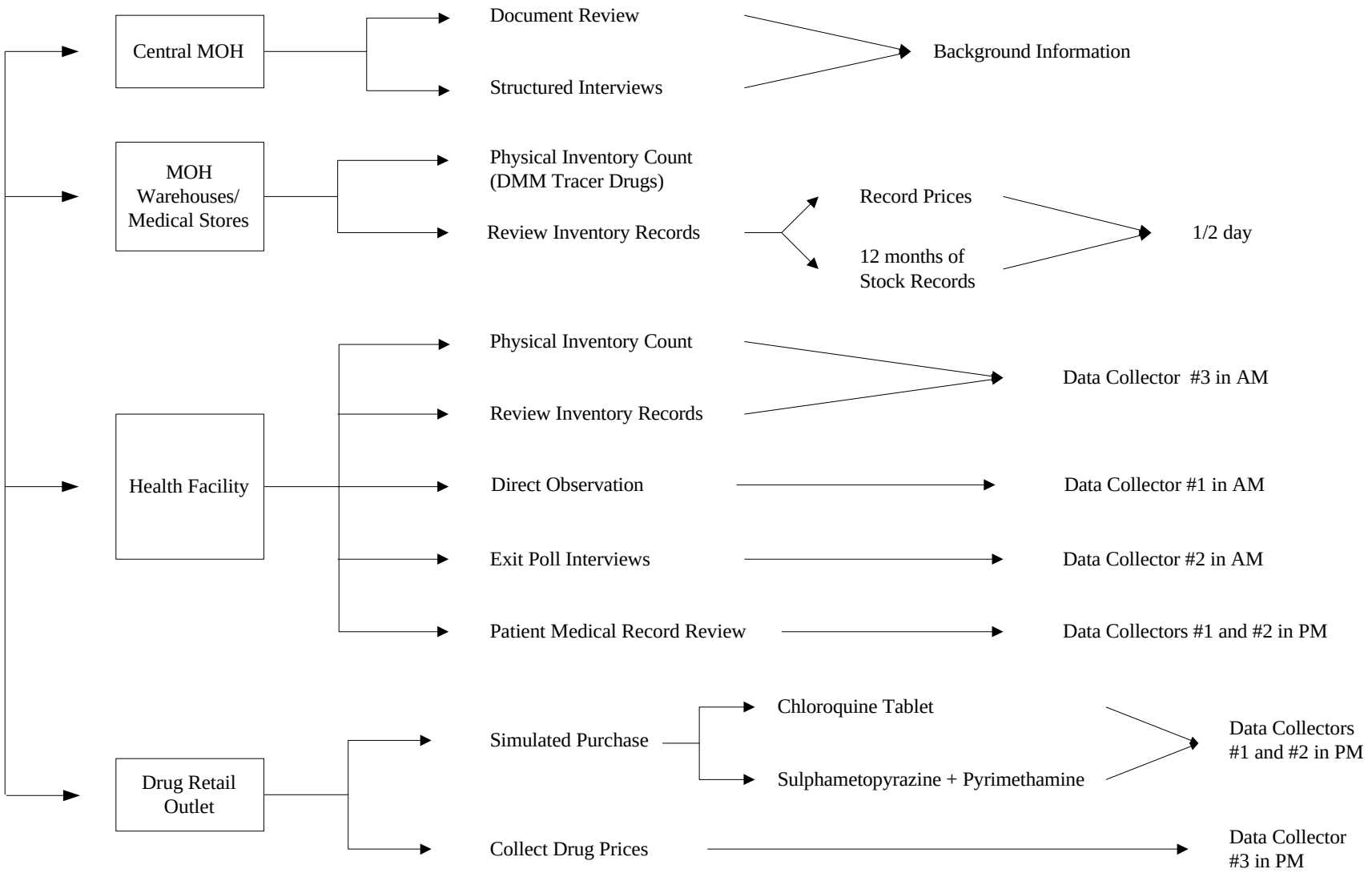
Letters of Authorization

One important detail that can cause serious problems if overlooked is letters of authorization. Each data collector, team manager, and investigator should be provided with letters from the appropriate authority (such as MOH), which introduce the bearer, request cooperation, and authorize data release. Letters from different authorities may be required for visits to health facilities and drug retail outlets. Whenever possible, central-level officials should inform the health facility authorities by telephone communication or radio prior to the arrival of the data collectors.

Summary of Data Collection Activities by Site

This chapter has described the different data collection activities that need to be carried out in the different target sites to complete the two-part assessment. To facilitate the planning of this effort, Figure 2 provides a graphic depiction of the entire data collection process in each of the sites. As depicted in Figure 2, data from the Central MOH and MOH Warehouses/Medical Stores can be collected prior to the field data collection at health facilities and drug retail outlets. The numbers 1, 2, and 3 to the far right refer to the team of three data collectors and their possible roles in the morning (AM) and afternoon (PM).

Figure 2. DMM Data Collection Process Flow Chart



Training Data Collectors

Recruiting and Training Data Collectors

It is necessary to recruit and train two groups of data collectors as follows:

- One group to collect data in health facilities and to obtain availability and price data in drug retail outlets
- Another group to carry out the simulated purchases

For the first group, the most effective data collectors will usually be doctors, pharmacists, nurses, or paramedical personnel who have worked in health facilities. There is some risk in using students or other parties who have no practical experience in working with the record-keeping systems that they will encounter. The risks are that the students will have difficulty identifying the required data, the work will be unduly slow and frustrating, and these factors could negatively affect the quality of the data. A related problem, which could produce similar results, lies in recruiting parties, particularly some doctors, who may consider themselves too senior to carry out the relatively tedious work required.

To minimize both risks and promote productivity, a useful strategy would be to pair health care providers and other workers with experience in storage facilities. This strategy would provide a team that has practical experience with product names as well as with both stock and clinical record keeping.

No matter who is recruited, however, it is essential that they be trained, and that the training include actual practice in filling out all forms required for both health facility and drug retail outlet data collection. Table 7 illustrates a model training course that may be adapted to suit local circumstances. A companion document, *DMM Data Collector's Guide*, is available to facilitate the training of data collectors and can serve as a guide to data collectors in their fieldwork.

Finding data collectors for the simulated purchases poses less of a recruiting problem. No technical expertise is required to do this quick and simple work. It is, however, very important to train the data collectors through role playing, and to verify that they understand what to do by observing their performance in two or three encounters in drug retail outlets. This observation can be set up with the help of a sympathetic store owner whose store could be used as a training site.

Training Tips

To make sure that data are collected as intended, it is necessary to provide data collectors with adequate training and practice before they begin work. This process helps build the necessary skills and confidence for the upcoming activities. In addition, using the data collection forms during training serves several purposes:

- Identifies and corrects questions that are inappropriate or unclear for the health setting
- Familiarizes data collectors with the questionnaires
- Provides a medium for learning and practicing data collection techniques

The amount of training will vary depending upon the caliber of personnel employed and the study methodology. For example, in-depth interviews require more elaborate training, but structured questionnaires require less training since they use focused questions.

To ensure that the training activity is carried out properly, the trainers should do the following in advance:

- Identify data collector team managers and data collectors and make assignments
- Identify a training venue that allows for flexibility in breaking up into small groups and gathering for lecture-style presentations
- Make necessary travel arrangements for data collectors to get to the training venue, if necessary
- Identify at least one health facility and one drug retail outlet convenient to the venue where data collectors can practice their work
- Make sufficient copies of all data collection forms and create individualized packets (see below)
- Prepare practice data for use in practical exercises and role playing
- Schedule training dates to allow sufficient time for all aspects of training

Data collector's packet contents should include the following (contents may vary depending on the country-specific situation):

- A copy of the data collector's guide containing a complete set of the data collection forms
- Letter of introduction from a recognized authority to introduce the data collectors to the health facilities
- Contact information of the team manager (name, phone number)
- Data collection schedule
- Notebook for taking field notes, two pens, paper clips for securing forms

Data Collection Team Managers

Depending on the context (size of region, number of data collectors, etc.), it may be useful to build a team of managers. The team managers should meet at least one day in advance of the training in order to—

- Be briefed on all aspects of the study (background, objectives, methods)

- Review role and responsibilities of the team managers (these should be written)
- Review assignments of sites and data collectors
- Be briefed on how to handle problems such as participation refusals
- Review training program

To carry out both the Drug Availability and Drug Use Studies, a team of at least three or four data collectors (with one person serving as team manager) is needed, particularly for the observation and exit interviews in health settings. For example, one option for a three-member team's division of data collection responsibilities in a health facility is as follows:

One person is team manager. He or she preselects patients that match the investigated diseases and reviews the checklists for completeness. Another data collector observes the consultation of the preselected patients, and the third one conducts the exit interview with the same patients. The team manager can collect the availability data and interview the clinic staff on standard treatments while the two other surveyors collect simulated purchase data at the drug retail outlet.

The team managers are preferably selected by the coordinator of the study and are usually senior personnel who have extensive knowledge of the health system or who have worked or are still working in health facilities. The decision to have data collection teams of three or four people should depend on the country-specific situation and should be determined by the study coordinator.

Training Techniques

To assist in the training process, following are a few general points about training adapted from the *Drug Supply Management for First-Level Facilities Training Guide* developed by Basic Support for Institutionalizing Child Survival (BASICS) and WHO (1996):

Help Data Collectors to Use the Forms Correctly

The data collector may need only a small bit of information to use a particular form correctly. However, if the data collector is not familiar with certain terms or items on the forms, clarify them. There is a good chance that if one data collector is not familiar with the terms or items, others are having the same problem.

Check the Data Collector's Understanding

A data collector may not understand a procedure and may need individualized help. The data collector may be inexperienced, tired, or less educated than the other data collectors. Be patient, and—

- Show the data collector where to find the material in the *DMM Data Collector's Guide.* Explain that all the necessary information can be found in the *Guide*. Ask him/her to reread the appropriate part.

- Ask the data collector why he/she is having a problem. Listen carefully. Help the data collector to think through the problem and propose his or her own solutions.

- Encourage the data collector to ask specific questions about how to perform a particular data collection technique.

Giving Feedback

The data collectors will be involved in active learning throughout the workshop. Give them feedback as they review the forms and practice the different data collection techniques. Always give constructive feedback. The feedback should occur while or after the participant does the activity, such as completing a question-and-answer exercise, using a checklist, or acting in a role play. It should include showing the participant how to do the activity correctly and giving the participant practice doing the activity himself or herself.

Steps for Leading a Simulation or Role Play

Several of the data collection techniques will require data collectors to observe and interview health care workers and patients or caregivers of patients. Some data collectors will also be required to pose as patients or caregivers to conduct the simulated purchases. Role play can be a useful training tool to help data collectors become familiar with such data collection situations. To conduct the simulation or role play:

1. Introduce the activity and state its purpose. Give data collectors as much instruction and background information as necessary. Tell them to refer to their *Data Collector's Guide*. If necessary, demonstrate how to perform the activity.

2. Assign individual roles and responsibilities. Hand out any necessary supplies or props.

3. Give data collectors enough time to prepare. You can estimate the time if you have practiced the activity yourself prior to the training workshop. Remind data collectors to work together to develop simulations and role plays.

4. Arrange the room so that the presenting group is separated from the others. Make sure everyone is able to see the simulation or role play.

5. After groups are prepared, introduce the simulation or role play.

- In a simulation, describe the order in which the groups will present their work.
- In a role play, introduce the players and their parts. Remind those data collectors involved in a role play to speak loudly so everyone can hear.

6. Begin the activity. Ask the groups to present the simulation or role play.

7. Instruct data collectors observing the activity and take notes during the activity for later discussion. Interrupt only if participants are not able to complete the activity.

8. When the activity is finished, thank the group. Ask participants to comment on aspects of the activity that were successful. Then ask about and discuss those parts of the activity that could be improved. Be supportive.

9. Lead a discussion among the data collectors. Conclude the activity by asking data collectors what they have learned.

Following are brief "how to" instructions for data collectors. Review these instructions with the data collectors. The simulation and/or role play exercises can be used to test how well data collectors perform different data collection techniques.

To collect data using the **direct observation** technique, do the following:

- Review the DUS-2: Observation of Health Worker Data Form before the consultation begins.
- Ask the health worker whom you will observe to explain the purpose of your presence in the examination room to the patient and caregiver, i.e., conducting a health care survey.
- Fill in the information at the top of the form to identify the facility, patient, and data collector.
- Once the consultation begins, do not speak since it might interfere with the patient-provider relationship.
- Start counting the time required for the consultation.
- Record the patient's reason for coming to the health center, i.e., the health problem.
- During the consultation, indicate which questions the health worker asked the patient or caregiver.
- During the consultation, record the information about all drugs prescribed by the health worker.
- Record the diagnosis made by the health worker.
- Record the total amount of time required for the consultation.
- Do not leave any spaces blank or unanswered questions on the forms unless the health worker did not ask the question or provide the information to the patient or caregiver.
- Record any problems encountered.
- Give the completed data forms to the team manager for quality checking before leaving the facility and record any refusals or problems.

To collect data using the **interview** technique, do the following:

- Review the DUS-3: Exit Poll Interview Form before the interview begins.
- Wait for the patient/caregiver to leave the health center.
- Preference is to interview those patients who were participants in the health care study.
- Explain the purpose of your interview, i.e., conducting a health care survey.
- Fill in the information at the top of the form indicating the facility, patient, and data collector.
- Ask patient/caregiver what was the chief complaint or reason for the consultation, i.e., the health problem.
- Ask the patient/caregiver, "What drugs were prescribed during the consultation and how are you going to take/give the drugs to your patient/child?"
- Record each drug mentioned by the patient/caregiver and how they will be taken/given to the patient.
- For each drug mentioned, ask if the caregiver already received the drug from the health center or pharmacy and record on the form.
- Do not leave any spaces blank or unanswered questions on the forms unless the caregiver does not know any of the information.
- Record any problems encountered.
- Give the completed data forms to the team manager for quality checking before leaving the facility and record any refusals or problems.

To collect data using the **record review** technique, do the following:

- Review the forms DAS-2, DAS-3, DAS-4, and DUS-1 before starting data collection.
- Based on sample size and time frame of the study, select the MOH records to be studied.
- Record the facility, data collector, and record system information at the top of the forms.
- For each antimalarial drug on the list, record all requested information.
- On form DUS-1, fill in each drug and the requested prescribing information on the form as ordered in the patient record.
- Do not leave any spaces blank unless the information is not documented in the records you are reviewing or is not available for use in the study.
- Record any problems encountered.
- Give the completed data forms to the team manager for quality checking before leaving the facility and record any refusals or problems.

To collect data using the **simulated purchase** technique, do the following:

- Review form DUS-4 before beginning data collection.
- Review the scenario for uncomplicated malaria located in the *Data Collector's Guide* before beginning data collection.

- Based on the sampling plan established for the study, go to the drug retail outlet.
- Make sure you have enough money to purchase any drugs recommended by the drug seller.
- Enter the drug outlet as would any normal client.
- Describe the condition of your patient to the drug seller and ask for recommendations.
- Purchase any drugs or supplies recommended by the drug seller.
- Immediately upon leaving the drug outlet, record the questions asked and recommendations made by the drug seller on form DUS-4 as appropriate.
- For each drug recommended, record the drug name and how the drug seller recommended giving the drug to the patient, i.e., dosage, frequency, duration, special considerations.
- Answer all questions on the forms and do not leave any spaces blank about how to give a drug, unless the drug seller did not give that information.
- Record any problems encountered.
- Give the completed data forms to the team manager for quality checking before leaving the location and record any refusals or problems.

To collect data using the **simulated patient** technique, do the following:

- Review form DUS-5 before beginning data collection.
- Review the scenario for uncomplicated malaria located in the *Data Collector's Guide* before beginning data collection.
- Based on the sampling plan established for the study, go to the health facility.
- Enter the health facility as would any normal patient/caregiver.
- Describe the condition of your patient to the health worker and ask for recommendations.
- Have any drugs recommended by the health worker dispensed at the health facility, if available.
- Immediately upon leaving the health facility, record the questions asked and recommendations made by the health worker on form DUS-5 as appropriate.
- For each drug recommended, record the drug name and how the health worker recommended giving the drug to the patient, i.e., dosage, frequency, duration, special considerations.
- Answer all questions on the forms and do not leave any spaces blank about how to give a drug, unless the health worker did not give that information.
- Record any problems encountered.
- Give the completed data forms to the team manager for quality checking before leaving the location and record any refusals or problems.

Data Collection in Health Facilities—Practice Session

A half day may be dedicated to practicing data collection in a local facility. Data collectors should be split up into small groups and assigned the task of completing some of the forms. They should be required to debrief the other data collectors afterward on the experience.

Once back in the training venue, the groups should present their "findings" with respect to ease of finding the required data, data entry, time required to complete the task, and other observations. After all groups have completed this presentation, groups should exchange their completed data collection forms. Groups will review the forms and critique them for completeness, legibility, and other relevant observations.

Testing Reliability of Data Collected on Observation Checklists

Even though you may have confidence in the ability of the surveyors you have selected to participate in a study, data collection can be a major problem when using observation checklists, such as form DUS-2. For example, when recording data on an observation checklist, surveyors may check off what they *think* they see and hear, instead of what is actually taking place or being said.

For that reason, initial training should include checking for intra- and inter-reliability of surveyors. The challenge of training surveyors in the use of observation checklists is twofold:

- To ensure that one surveyor consistently checks the same thing every time he or she observes the same thing (**intra-surveyor reliability**)

- To ensure that different surveyors consistently check the same answer every time they observe the same thing (**inter-surveyor reliability**)

The goal of reliability checking is to obtain more than 90 percent intra- and inter-surveyor reliability in three consecutive role plays before the surveyors go out for data collection. Use the form that follows these instructions (Reliability Check Form) to record results of role playing during surveyor reliability checks.

Instructions for using the **Reliability Check Form**:

1. On the copies of form DUS-2 that will be used for training, number the individual items observed.
2. Write the numbers of all the observation questions in the far left column labeled *Quest. # .*
3. Place the code or name of each surveyor in the columns immediately below *Data Collector Code or Name,* one per column.
4. Record the number of the role play in the space at the bottom of the form beside the label *Number of the reliability check,* since the role plays will be repeated twice.

5. Have the surveyors observe a role play while filling out the data observation questionnaire (form DUS-2). A referee observes the same role play and fills out an observation questionnaire that will serve as reference or standard for comparing the surveyors' answers.
6. Collect all questionnaires.
7. Write the referee's answer to each question in the column labeled *Ref. Ans.* The referee should be experienced in observation of health workers.
8. For each question, write each surveyor's answer to the question in the column under his or her code or number.

Calculate the **inter-surveyor reliability** as follows:

For each question, count how many surveyors gave the same answer as the referee, and count the total number of surveyors. Calculate the inter-surveyor reliability (Q%) for each question using the following formula:

$$Q\% = \frac{\text{Number of Surveyors with the Same Answer as the Referee}}{\text{Total Number of Surveyors}} \times 100$$

Place the result for each question in the column labeled *Q %*. A question with less than 90 percent reliability should be reviewed with the group for clarity of the instructions. It may be necessary to adapt the question. This procedure should be repeated until all questions get an acceptable percentage (usually >90%).

Calculate the **intra-surveyor reliability** as follows:

For each surveyor, count the number of questions where the surveyors answered the same as the referee, and count the total number of questions on the form. Calculate the intra-surveyor reliability (S%) for each question using the following formula:

$$S\% = \frac{\text{Number of Questions Where Surveyor Answered Same as the Referee}}{\text{Total Number of Questions on the Form}} \times 100$$

Place the result in the row labeled *S %*. This is the intra-surveyor reliability for each surveyor. A surveyor that has less that 90 percent should receive additional training before continuing.

Calculate the **average reliability for the group of surveyors** as follows:

$$\text{Average \% (reliability)} = \frac{\text{Sum of all S\%}}{\text{Total Number of Surveyors}} \times 100$$

Place the average % in the space at the bottom of the form beside the label *Reliability (average % for the group).* The role plays should be repeated a total of three times, and surveyors should obtain more than 90 percent for three consecutive simulations before deciding that the observation questionnaire is well understood.

At the end of the training, surveyors who do not have a score of 90 percent should either not be used as surveyors or should be assigned to tasks that don't involve filling out the observation checklist.

Since reliability checking is practically the only measure for the quality of data obtained during the direct observation technique, it pays to spend a little more time during training to reach the necessary reliability level before going to the field for data collection.

Note: The same reliability exercise can be applied during training for other data collection techniques like interviews and record reviews. However, inter- and intra-surveyor reliability should be close to 100 percent for these techniques before sending surveyors to the field.

Figure 3. Reliability Check Form for Data Collectors' Training

Quest. #	Ref. Ans.	Data Collector Code or Name												Q %
S%														
Number of the reliability check:						**Reliability (avg. % for the group):**								

Training Schedule

The following (Table 7) is a schedule of training activities to use in training data collectors for the two-part study of health centers and drug retail outlets.

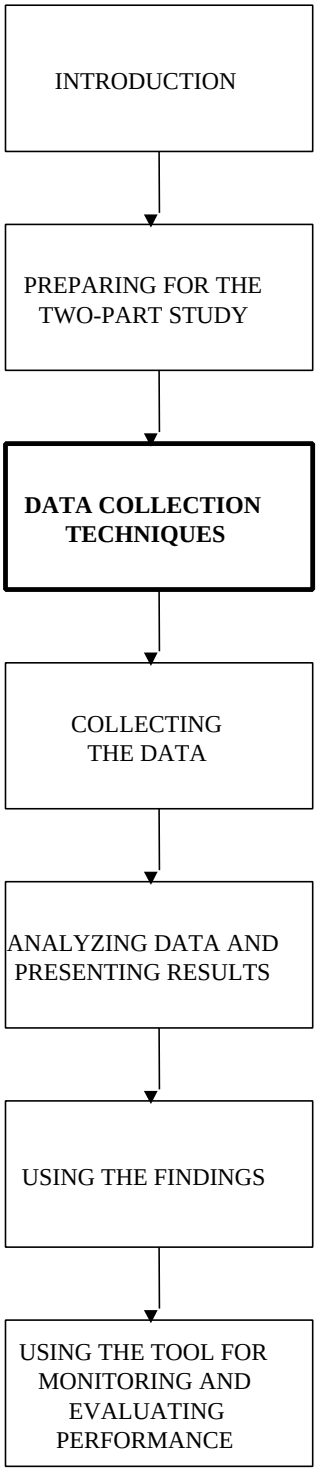
Table 7. Illustrative Four-Day Training Course for Data Collectors in Health Facilities and Drug Retail Outlets

Day	Training Activities	Time
1	1. Opening—Introduction of the data collectors 2. General presentation: • Purpose of the survey: to document drug availability and drug use for malaria • Training objectives: to familiarize data collectors with survey questionnaires and data collection techniques • Introduction of the Data Collector's Guide • Where to collect data: health facilities and drug retail outlets • Data collection techniques to use: direct observation, interviews, simulated purchases, record reviews, simulated patients • Discuss data collectors' expectations or concerns 3. Work schedule and compensation 4. Location of sites to be surveyed	1 to 2 hours
	5. Review survey form DAS-1: General Data Collection Preparation Checklist 6. With the remaining survey forms grouped according to where data are to be collected, review them one by one as follows: <u>Central Medical Stores/Regional Medical Stores</u> • DAS-2D: Inventory Data Form • DAS-3: Stock-Out Data Form • DAS-4: International Price Comparison Form <u>MOH Health Facilities</u> • DAS-2A-D: Inventory Data Form • DAS-3: Stock-Out Data Form • DAS-4: International Price Comparison Form (optional) • DUS-1: Medical Records Review Form • DUS-2: Observation of Health Workers Data Form • DUS-3: Exit Poll Interview Form • DUS-5: Simulated Patient Data Form <u>Drug Retail Outlets</u> • DAS-2E: Inventory Data Form • DUS-1: Medical Records and Facility Review Form (drug price information) • DUS-4: Simulated Purchase Form	2 to 3 hours

Day	Training Activities	Time
1	7. Central medical stores/regional medical stores visits: • Practice filling out survey forms DAS-2, DAS-3, and DAS-4 • Practice role play for forms DAS-2, DAS-3, and DAS-4 8. MOH health facility visits: • Practice filling out survey forms DAS-2, DAS-3, DAS-4, DUS-1, DUS-2, DUS-3, and DUS-5 • Practice role play for forms DAS-2, DAS-3, DAS-4, DUS-1, DUS-2, DUS-3, and DUS-5 in small groups 9. Drug retail outlet visits: • Practice filling out survey forms DAS-2E, DUS-4 • Practice role play for forms DAS-2E and DUS-4 in small groups 10. Discuss policy of patient confidentiality	2 to 3 hours
2	1. Practice how to draw a sample of patient encounters from health facility records 2. Visit predetermined health facilities and collect a complete set of data using survey forms: DAS-2, DAS-3, DAS-4, DUS-1, DUS-2, DUS-3, and DUS-5	1 hour 5 to 6 hours
3	1. Debrief on health center practice visits: critique performances and troubleshoot problems 2. Discuss revisions of forms if any are necessary as a result of the practice visits 3. Role play in small groups—check reliability (quality) of data collector knowledge, skills, and abilities for filling in the data collection forms 4. Visit predetermined drug retail outlets and collect a complete set of data using DAS-2E, DUS-1 (prices), DUS-4	3 to 4 hours 2 to 3 hours

Day	Training Activities	Time
4	1. Debrief on drug retail outlet practice visits: critique performance and troubleshoot problems. 2. Discuss revision of forms if any are necessary as a result of the practice visits 3. Role play in small groups—check reliability (quality) of data collector knowledge, skills, and abilities for filling in the data collection forms	1 to 2 hours
	4. Assign data collectors to teams and appoint team manager for each team 5. Discuss purpose of regular team meetings during data collection: to discuss successes, problems, and how to overcome data collection problems 6. General review and open questions	3 to 4 hours
	7. Review supervisory role with all team managers. They should— • Observe data collectors periodically • Ensure completeness of data collection forms before leaving the facility • Know how to fill out shaded areas of data collection forms and establish standardized coding for identifying individual data collectors, patient records, encounters, etc. • Know how to select an alternate health center when one becomes inaccessible to data collectors • Clean up data forms before data analysis	1 to 2 hours

DRUG MANAGEMENT FOR MALARIA MANUAL



Chapter 3.

DATA COLLECTION TECHNIQUES

Data for calculating the 13 indicators are collected using eight different data collection techniques at central, regional, health facility, and drug retail outlet levels. The eight techniques are structured interviews, document review, physical inventory checks, records review, simulated purchases, simulated patients, direct observation, and exit polls. Some of the techniques will be used at more than one level. Table 8 lists the data collection techniques used in each study. The *Data Collector's Guide* provides data collection forms and checklists as well as a detailed description for each technique.

Structured Interviews

Structured, key-informant interviews are person-to-person discussions used to gather information and documentation. The most important aspect of the interview is asking questions in a structured or standardized way. Using a questionnaire during the interview will help the data collector/interviewer organize his or her thoughts. The questionnaire (see sample in the *Data Collector's Guide*) can also serve as a checklist to ensure that all the topics for which the data collector needs information are covered. To carry out this work, it is important to keep two points in mind:

(1) Informants should be selected for their knowledge about the issues and their ability to provide current and reliable data. The selection of informants should also take into consideration their official position and factors that may bias their views.

(2) To the extent possible, data collected through interviews should be verified through review of documents or records.

Table 8. Data Collection Techniques

Study	Techniques
Drug Availability Study	Structured interview
	Document review
	Inventory check in medical stores
	Inventory check in health facilities
Drug Use Study	Patient medical record review
	Simulated purchases
	Simulated patients
	Direct observation
	Exit poll interviews

Document Review

Chapter 2 outlines several planning activities to conduct the two-part study (see Table 3). Reviewing documents to collect country-specific vital statistics and background information, as well as data on MOH pharmaceutical operations, is an important part of the planning. Tables 1, 2, and 3 provide guidance on what information to collect. It is important to remember that information gathered during one-on-one interviews should be confirmed or supported through documentation. Also, always make sure to note the date and have an understanding of the context (e.g., regional versus national, public versus private) for the data or documents collected.

Physical Inventory Checks

The physical inventory and review of records take place in MOH storage and health facilities as well as drug retail outlets. The physical inventory and review of stock records serve as a "point- in-time" check that is carried out by examining the bin card and the stock card records of each DMM tracer drug item in stock. A physical count of stock on hand will be necessary to check that the stock balance records are correct. Conducting the physical inventory check in MOH facilities will provide an additional form of evaluation that may reveal defects in the warehousing system and identify surplus, expired, and obsolete stock.

Patient Medical Records Review

Patient medical records serve as the primary source of retrospective data on the prescribing practices used to treat malaria. Chapter 2, Preparing for the Two-Part Study, describes how the records will be selected.

Simulated Purchases

The simulated purchases technique is when data collectors pose as ordinary customers and attempt to purchase treatment for a certain condition. Simulated purchases are used rather than direct observation because observation requires the observer to stay at the site for a period of time. In a retail setting this presence may be disruptive to customer service and would probably cause the drug sellers to modify their behavior. Also, if asked directly, drug sellers are likely to inaccurately report their practices. Experience in a number of countries shows that there are usually significant differences between drug sellers' reported and observed prescribing practices. Using simulated purchases should minimize both the problems of bias in the study and the inconvenience to the drug seller or drugstore manager.

Simulated Patients

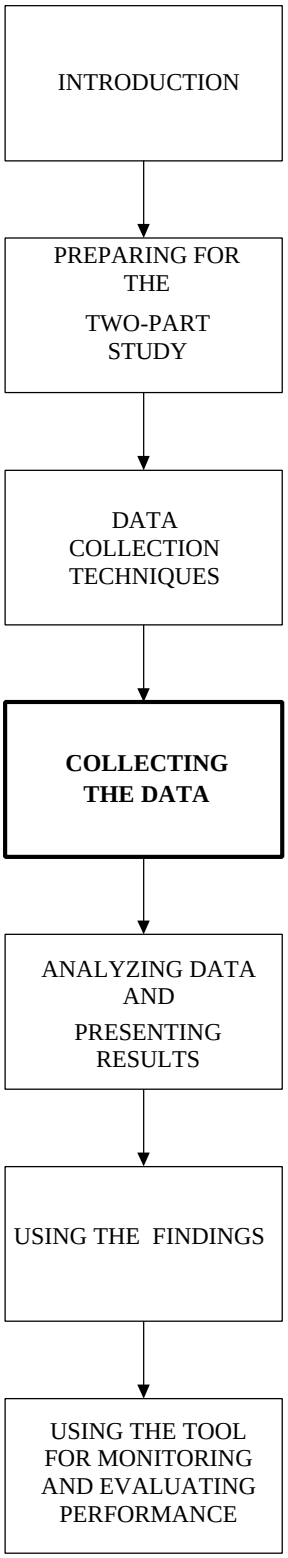
The simulated patient technique is when data collectors pose as ordinary patients/caregivers and attempt to receive treatment for a certain condition. Simulated patients are used rather than direct observation because observation requires the observer to stay at the site for a period of time. This presence may be disruptive to normal service and would probably cause the health workers to modify their behavior. Also, if asked directly, health workers are likely to inaccurately report their practices. Experience in a number of countries shows that there are usually significant differences between health workers' reported and observed prescribing practices. Using simulated patients should minimize both the problems of bias in the study and the inconvenience to the health worker and patient.

Direct Observation

Direct observation is a data collection technique used in the Drug Use Study. Structured observations require the data collectors to directly observe the behavior of the health workers for the purpose of describing particular prescribing practices. The data collector will use a guide to record whether or not certain events have taken place. The process is described in greater detail in Chapter 4, Collecting the Data, in the section titled Define Methods for Drug Use Study.

Exit Poll Interviews

Exit poll interviews are used in the Drug Use Study. Malaria patients and caregivers of children and adults who are sick with malaria are the target audience for the exit poll interviews. The purpose of the exit poll interviews is to determine how well each patient/caregiver understood the instructions given by the health worker or drug dispenser about the medicine prescribed, about follow-up care in case of worsening conditions, and whether the patient/caregiver has obtained the required medication. This subject is explained in more detail in the *Data Collector's Guide*.


INTRODUCTION
PREPARING FOR THE TWO-PART STUDY
DATA COLLECTION TECHNIQUES
COLLECTING THE DATA
ANALYZING DATA AND PRESENTING RESULTS
USING THE FINDINGS
USING THE TOOL FOR MONITORING AND EVALUATING PERFORMANCE

Chapter 4.

COLLECTING THE DATA

Define Methods for Drug Availability Study

The purpose of conducting the Drug Availability Study is to determine the degree to which the drugs and supplies needed for treating and preventing malaria are available. Reaching that goal will require collecting information and data that will allow the investigator to calculate or derive the indicators listed in Chapter 1 and to answer the following questions:

1. Are the drugs and medical supplies required to treat malaria available in public health facilities?

2. What are the determinants of product availability in the public sector and what can be done to bring about improvement?

By conducting an accurate and systematic assessment of the logistics supply system for drugs and supplies used for malaria, the investigator will identify specific strengths and weaknesses of the system and, in the process, gather information that will be useful in planning corrective interventions for weaknesses identified in the system.

Before data collection begins, it is critical to the success of the Drug Availability Study that investigators and other study team members complete the planning steps outlined in Chapter 2. To summarize, investigators should have planned a schedule for collecting the following information:

- Vital statistics and background information such as exchange rates, national and regional population figures, incidence of major health problems, and so forth. Refer to Tables 1 and 2 in Chapter 2.

- Overview of MOH pharmaceutical management operations such as schematic of flow of drugs, transport, delivery schedules, numbers and locations of MOH health facilities, budgets at central and regional levels, numbers and locations of drug wholesalers, distributors and manufacturers, drug cost recovery systems, etc.

Once this information has been collected, it should be distributed to the investigators prior to the start of data collection.

An important point to understand and remember while conducting the Drug Availability Study is that malaria drugs and supplies may have different channels of distribution. For example, in some countries the vertical malaria program may have a distribution system distinct from the MOH's routine system for delivering drugs. In other countries all drugs and supplies may go through the MOH system alone. It is important, therefore, to be aware of this and to collect all the information that is needed to provide a "complete" picture of the logistics system for all DMM antimalarial drugs.

Sites for data collection are specified for each of the five drug availability indicators. In general, the data collection sites for the DMM indicators include MOH central offices, central and regional medical stores, and health facilities. Among these sites, three different data collection techniques will be used to gather information for deriving or calculating the DMM availability indicators. These techniques include document review, structured interviews, and physical inventory checks. Table 9 summarizes the data collection sites, techniques, and forms for the Drug Availability Study.

Select the Study Time Period

Several of the availability indicators are based on a retrospective review of stock records. For the drug management assessment, investigators should select a study time period to cover the last consecutive 12 months or an equivalent period of time. It is important for all data collectors to use the same 12-month time period to ensure that the data received from all sites are comparable. Therefore, the time period should be decided prior to the start of the data collection process, and every data collector should know the agreed-upon time period.

Table 9. Data Collection Sites and Techniques for the Drug Availability Study

Data Collection Sites	Data Collection Techniques	Data Collection Forms
Ministry of Health Central Offices	Structured Interviews and Document Review	DAS-4
Ministry of Health / Central Medical Store	Physical Inventory Check and Records Review	DAS-2, DAS-3
Regional Medical Stores	Physical Inventory Check and Records Review	DAS-2, DAS-3
Health Facilities	Physical Inventory Check and Records Review	DAS-2, DAS-3
Drug Retail Outlets	Physical Inventory Check	DAS-2

Define Methods for Drug Use Study

As mentioned earlier, the purpose of the Drug Use Study is to assess the clinical and cost implications of prescribing practices for selected childhood illnesses. For these conditions, study investigators will gather data from records available in health facilities to calculate or derive results for the DMM indicators.

1. What are current prescribing practices for malaria?

2. Are the current prescribing practices clinically appropriate?

3. How does the drug cost of current practices for treating malaria compare to what the cost would be if malaria treatment guidelines are followed?

4. Are drugs required to treat malaria available and affordable in the private sector?

Sample Size

An important step in planning for the Drug Use Study is determining the appropriate sample size. For the Drug Use Study in health facilities, two of the four sampling design steps discussed in Chapter 2, that is, selection of the health facility sample and selection of the patient encounter sample, will apply to this portion of the assessment.

The sample size used in this manual for health facilities is 20, 5 from each of the four selected geographic regions of the country. Chapter 2 details the steps for actually making the site

selections. Patient encounter sampling is addressed in the following sections on Retrospective and Prospective Data Collection.

Data Collection in Health Facilities

In general, there are two options for collecting drug use data: prospectively through observation and simulations and retrospectively through records. Prospective data collection through observational methods for morbidity-specific analysis is expensive and time-consuming because it is necessary to remain at one site until a sufficient number of cases for the target health problem have been observed. This drawback may be particularly problematic when observing for a single disease such as malaria. However, prospective methodologies can provide useful information about the diagnostic process and on the communication between health providers and patients. The retrospective method, through a review of facility registers, patient records, or dispensing records, is less time-consuming, less expensive, and can describe practices over a longer period of time. However, the information provided in records is often incomplete. The *DMM Manual* uses both forms of data collection.

Retrospective Data Collection in Health Facilities

To gather information for Drug Use Study indicators 5 through 13, data collection will involve a retrospective review of patient records in MOH health facilities. The retrospective method of data collection requires that adequate sources of data exist. For the purposes of this study, the records should allow selection of a random sample of patient encounters within a defined period of time. The records should also include the specific names, strengths, and routes of administration of all drugs prescribed.

For each category of malaria studied through retrospective data collection, a minimum of 600 patient encounter records must be reviewed. This number is achieved by randomly selecting 30 medical records for each malaria category problem in each of the 20 health facilities. Examples of patient encounter records include daily registers, medical records, or prescription slips.

N REMEMBER

Potentially, there are two categories in the study: uncomplicated malaria and giving prophylaxis to pregnant women as presumptive treatment. Therefore, a total of 1,200 patient encounter records (30 randomly selected records from each facility for uncomplicated malaria and 30 for presumptive treatment given to pregnant women during antenatal care) are needed. Indicator 13 (pregnancy), however, should only be used if it is in line with government policy

Organizers should also as a group discuss and reach consensus on a list of local terms used to describe symptoms that may be listed in health facility records to denote malaria. This list can be used as a reference by data collectors.

Based on experience in a number of countries, the following steps are suggested:

Step 1: Begin by extracting, from the facility's patient register, a list of names of at least three patients per month for malaria, for the most recent 12 months prior to the time of the study. Start with the most recent full month and work backward (e.g., October 1999, September 1999, August 1999, etc.).

Step 2: In rare cases, most or all of the data required may be found in the register. More commonly, however, it is necessary to consult the individual patient records and/or dispensary records. Make sure to check the quality of the records (in terms of completeness) first before selecting the record as an encounter to include in the data sample.

Step 3: In either case, the next step is to select from the list of names the records that contain information (that is as complete as possible) for at least two patients per month during the low season and four patient records per month during the high season for malaria. For instance, where the high-season malaria months are from March to June, the data collectors will randomly choose four records (as described above), while for the months from July to February, the data collectors will randomly choose two records. If there is no seasonality involved in the occurrence of malaria, the data collectors will randomly choose three records per month, that is, a total of 36 records.

Step 4: To use a random process for selecting names from malaria encounters recorded in the facility's patient register, follow the interval method of sampling described in Chapter 2. To summarize, for each month (using the list of local terms the study team has developed to identify malaria), group the encounters according to malaria, etc. For each month—

- Total the number of encounters for malaria.
- Select every n^{th} encounter, where n is determined by dividing the number of encounters identified for that month by three. For example, if 25 malaria encounters were identified for the month of October, divide 25 by 3 to equal 8.3. Then, select every eighth encounter to randomly identify the three encounters needed for malaria in the month of October.
- Carry out this same process for each of the remaining 11 months.
- Starting from the most recent case, the next step is to fill out the data collection forms, recording information until *complete data on all indicators* are collected for 30 outpatient contacts for malaria at each site.

N REMEMBER

The reason for beginning with the larger list of names (36 rather than the required 30) is that very often the records do not contain complete data for every contact, so a certain number of names for which data are incomplete will have to be discarded.

Incomplete Retrospective Data in Health Facilities

Very often, data from records are incomplete. This is particularly true for prescribing data such as the dosage regimen and duration of therapy. It will be rare to find retrospective data that contain all the information needed. The following algorithm is an approach that can be used to collect "proxy" data to fill in incomplete retrospective data. However, the obvious drawback to this approach is that with each progressive step the data collected are probably less and less close to the actual prescription pattern. The boxes contain the possible situations; the text beneath indicates what course of action could be followed. The *Data Collector's Guide* includes a data collection instrument that can be used to collect the data described below.

Retrospective data available in records over a period of 12 months, containing all necessary details.

Use retrospective method.

Records available over a period of 12 months, not containing all necessary details; prescriber can be interviewed.

Use retrospective method and interview the prescriber on what his or her normal prescribing practices are for each of the prescribed drugs, when prescribing for each of the categories. Apply his or her normal prescription pattern to all encounters and drugs where details are missing. Information collected through interviews should be circled to make the source of each piece of data clear.

Records available over a period of 12 months, not containing all necessary details; prescriber cannot be interviewed, but head of the outpatient clinic can be interviewed.

Use retrospective method and interview the head of the outpatient department on what the recommended prescribing practices are for each of the prescribed drugs. Apply his or her recommended prescription pattern to all encounters and drugs where details are missing.

Prospective Data Collection in Health Facilities

To gather information for Drug Use Study indicators 11and 12, a prospective method will be used.

The patient encounter sample size for observation-only indicator 12 is a special case. As discussed in the next section, a convenience sample of patients (those who happen to be available at the time of data collection) with malaria within each health facility will serve as the sample. Data collectors should aim to observe 10 to 15 patient encounters in each of the 20 health facility sites.

Review of Data Collection Techniques for Prospective Method in Health Facilities

Structured observation or simulated patient will be the data collection techniques used with the prospective method.[6] These techniques apply to Drug Use Study indicator 12.

Structured Observation

Observation requires the data collector to directly observe the behavior of the health worker(s) with the purpose of describing particular prescribing practices. For this study, the data collector will conduct a nonparticipant observation because the data collector will observe the health worker without interacting with the person being observed. The technique is considered structured because the observer, in this case the data collector, will observe events using a guide that has been planned in advance (i.e., based on the specific prescribing practices described in the indicators). The observer/data collector, as inconspicuously as possible, will record whether or not the events take place during the session.

To work, this technique requires qualified and reliable data collectors to serve as observers, a clear and informative observational guide, and the cooperation of those being observed. One factor that limits the objectivity of the process is the presence of the "non-interacting" observer. This person's presence may influence the behaviors of the person or events being observed. Thus, there is a level of bias in the process on the part of both the observer (subjective judgment regarding events being recorded) and the health workers being observed (may alter their usual performance to impress the observer). Data collectors should be trained to be neutral and nonjudgmental toward the person being observed.

[6] International Network for Rational Use of Drugs (INRUD) Social Scientists Working Group. December 1996. How to Use Qualitative Methods to Design Drug Use Interventions, Working Draft. Arlington, VA: Management Sciences for Health.

Prior to observing a consultation, the data collector must obtain permission to conduct these observations from the administration of the health facility and develop a method of identifying that the health problem of the patients is malaria. This can be done by asking each of the patients or caregivers directly about the nature of their complaint or ailment as they wait in the lobby. *All patients must be assured as to the confidentiality of the information provided.* Another option would be for the data collector to develop a master patient list that identifies each patient's age and chief complaint from the patient register and observe each of those consultations. Some methods may be applied more easily in larger facilities, while other methods may be more efficient in smaller facilities. Whatever the approach selected, it should first be discussed as a group among study team members and agreed upon prior to the start of the actual observations.

One of the challenges in using the prospective method in this setting is collecting data for a large enough sample size within the short time frame available for observation. As mentioned earlier, for this particular aspect of the study, a convenience sample of patients will serve as the data set. This may make it difficult to identify a large enough sample of cases. Therefore, the data collectors should include in the sample all malaria patients within each health facility. Although random selection would eliminate potential biases, given the limited data collection time period, using malaria as the only selection criteria is necessary to have a large enough sample size. Spending a half day of observation in each health facility should provide a representative data set to review the prescribing practices of health workers for malaria patients. While no firm rule exists, data collectors should try to observe 10 to 15 patient encounters in each of the 20 health facility sites to adequately describe the prescribing practices.

Two data collectors should work as a team. One data collector should be located in the examination room or area to observe and hear the health workers' interactions with patients. The data collector must be as unobtrusive as possible and not disrupt the consultation or bias the responses of the caregiver or the behavior of the health worker. A new observation questionnaire should be completed for each patient seen. The other data collector should be stationed outside of the facility to conduct exit poll interviews of patients as they leave.

To conduct the structured observations, follow these steps:

Step 1: As part of the study preparation, the study investigators, in collaboration with the data collectors, should develop the observation guide and exit poll interview guide. These guides should include a checklist of the specific prescribing practices to look for during the observation or to ask about during the exit poll interview. Forms DUS-2 and DUS-3 in the *Data Collector's Guide* can serve as models.

Step 2: Carefully select the data collectors who will serve as observers. To help ensure accurate data, observers should be familiar with the cultural background of the people being observed and be able to understand their language. They should also be familiar with pharmaceutical and general medical terms, and they should be able to sit quietly and observe without interfering.

Step 3: Train observers/interviewers and conduct a practice session to test the data collector's observation technique and exit poll interview skills, as well as the observation guide and exit poll interview survey. A sample observation guide (DUS-2) and exit poll interview survey form (DUS-3) are included in the *Data Collector's Guide.*

Step 4: Determine the encounter to be observed by identifying patients either in the health facility waiting area or as they are registered according to the description of the chief complaint. Once the patient has been identified, one of the observers should follow the patient/caregiver through the screening, examination, and treatment process until the patient leaves the health facility.

Step 5: Give the patients/caregivers a slip of paper to carry until they exit the facility. This will enable the data collector conducting the exit poll interviews to identify which patients/caregivers to interview. As the patient/caregiver leaves the facility, the other data collection team member should ask the patient/caregiver for the paper and record the same number on the exit poll interview survey form and proceed to conduct the exit poll interview. This process will allow data collectors to match the observation with the exit poll interview and assist in the comparison of what was said (or not said) to the patient/caregiver by the health worker and what was understood by the patient/caregiver.

Step 6: Analyze and interpret the observational findings.

Simulated Patient

This is a prospective data collection technique that involves a data collector assuming the role of either a caregiver or a patient at a health facility in order to gather data. The first step is to recruit the data collectors for simulated patients. They should be local people whose appearance and demeanor suggest that they are regularly employed, for example, as vehicle drivers or secretaries. As the gender of the data collector may affect results, make sure that all data collectors are of the same gender. Normally, women are the best choice.

The trained data collectors will have the task of presenting the scenario for uncomplicated malaria. All data collectors should be trained to carry out this scenario.

The data collector will assume the role of a caregiver of a patient with malaria and will seek advice at the selected health facilities as a normal patient waiting for a consultation.

To use the simulated patient data collection technique, train data collectors to follow the scenario below when attending health facilities:

Scenario for Simulated Patient: Uncomplicated Malaria

Present yourself as the caregiver of a 12-year-old girl who has had a fever on and off for a week. Use local terms to describe the symptoms of the child. Request advice regarding which drugs to give the child. Do not provide any additional information unless directly asked for more information. Take any prescription written by the health worker, remember any advice and/or directions given, and leave the health facility.

If the health worker asks these questions, reply as follows:

The condition of the girl: In addition to the fever, the child has complained of a headache and aches and pains since last week. She has been feeling generally unwell for a week.

If the girl took medication: Say that she took a full course of chloroquine a week ago. The fever went away after this, but returned three days later.

Can the girl take food and/or liquids: Say she is able to take both liquids and food.

Actions

Notice and remember the following (you can ask the health worker to repeat questions):

- Whether the health worker gave instructions on how to administer the medication
- Whether the health worker told you about the warnings associated with the product
- Whether the health worker gave other advice or information on how to care for the child and treat the fever episode
- The name(s) of the drug(s) prescribed

Write this information on data form DUS-5 after you exit and leave the area, but before you conduct the next simulated patient exercise.

Sample Size of Drug Retail Outlets

Chapter 2 provides a detailed discussion of sampling. To summarize, the best approach, from the point of view of representative sampling, is random selection of drug retail outlets within each of the four geographic areas in the sample design. The best way to accomplish this random selection is to apply the systematic interval sampling method to site lists, as described in Chapter 2. However, a simpler approach, from the logistical point of view, is to choose the site that is geographically closest to each randomly selected health facility visited. Sample 20 drug retail outlets and use the same 20 outlets for each of the simulated purchases scenarios, but employ different data collectors, one for each scenario.

Conduct Survey in Drug Retail Outlets

The first step in conducting the survey is to review the workplan with the rest of the study team. Make sure each data collector is familiar with the specific drug retail outlets to be surveyed and has a timetable of when the simulated purchases will occur. Each data collector should have enough money to make the purchases and the transportation and accommodation arrangements. As part of the review, also make sure all team members are familiar with and have enough copies of all the Drug Use Study data collection forms (and instructions) they need for each drug retail outlet to be surveyed.

Review of Data Collection Technique in Drug Retail Outlets

The data on the prescribing practices in drug retail outlets will be collected prospectively. The data collection technique used will be simulated purchases. The first step is to recruit the data collectors for simulated purchases. They should be local people whose appearance and demeanor suggest that they are regularly employed, for example, as vehicle drivers or secretaries. The gender of the data collector may affect results; therefore, make sure that all data collectors are of the same gender. Normally, women are the best choice.

The trained data collectors will have the task of presenting the scenario for uncomplicated malaria. All data collectors should be trained to carry out this scenario.

The simpler selection approach of choosing the site that is geographically closest to each randomly selected health facility visited should be used if possible. The data collector will leave the study health facility, turn right, walk to the nearest drug retail outlet, and simulate the purchase according to the standard scenario for malaria. Then, the data collector will return to the study health facility and, this time, turn left and walk to the nearest retail outlet, where he or she will simulate the purchase according to the standard scenario. Working in teams of two, the data collectors should decide in advance who will conduct the scenario for each specific drug retail outlet.

To use the simulated purchases data collection technique, train data collectors to follow the scenario below when visiting drug retail outlets:

Scenario for Simulated Purchases: Uncomplicated Malaria

Present yourself as the caregiver of a 12-year-old girl who has had a fever on and off for a week. Use local terms to describe the symptoms of the child. Request advice regarding which products to give the child. Do not provide any additional information unless directly asked for more information. Purchase the drugs recommended by the retail drug seller and leave the shop.
If the drug seller asks these questions, reply as follows:

The condition of the girl: In addition to the fever the child has complained of a headache and aches and pains since last week. She has been feeling generally unwell for a week.

If the girl took medication: Say that she took a full course of chloroquine a week ago. The fever went away after this, but returned three days later.

Can the girl take food and/or liquids: Say she is able to take both liquids and food.

Actions

Notice and remember the following (you can ask the drug seller to repeat questions):

- Whether the drug seller gave instructions on how to administer the medication
- Whether the drug seller told you about the warnings associated with the product
- Whether the drug seller gave other advice or information on how to care for the child and treat the fever episode
- The name(s) of the product(s) recommended to purchase

This information should be written on data form DUS-4 after exiting and leaving the area, but before conducting the next simulated purchase.

Collect Drug Price Data in Drug Retail Outlets

As part of the process of conducting reviews of medical records in health facilities (DUS-1 Medical Records and Facility Review Form), a record of the drugs prescribed will be developed. To collect data on the retail prices for these drugs, a data collector should follow these instructions: visit the drug retail outlets, ask the drug seller the price for each drug, and record the sales prices on DUS-1. If an item is not stocked, skip that drug and go on to the next one. Where a site stocks more than one brand of the same product, record the name and price of the least expensive product. For drugs that are repeated on DUS-1, only record the price the first time it appears on the form. The prices collected on this form will be used to calculate the costs for indicator 10, average cost of drugs prescribed as a percentage of costs if Standard Treatment Guidelines for treating malaria were followed.

Conduct Survey

As part of the planning process, a workplan should be completed that includes all the specific sites, facilities, departments, and personnel to be visited, a timetable of when the visits will occur, the assignment of teams to specific locations or areas, and the transport and accommodation arrangements. In preparation for conducting the survey of MOH offices, facilities, and drug retail outlets, it is important to review the workplan with the whole study team. Maintaining a high level of open communication among study team members and making sure that all team members know their respective responsibilities will help to minimize problems during the data collection process.

Before sending data collectors into the field, study investigators should make sure that each person is familiar with and has enough copies of all the data collection instruments they will need

for the site(s) that person is responsible for. Explicit, written instructions for using the data collection instruments should be given to each data collector. Samples of written instructions are included with the respective samples of data collection instruments in the *Data Collector's Guide*.

Supplies such as pens, notebooks, bags for carrying forms, etc., should also be given to each data collector. Study investigators should also make sure that all the site visits have been approved and scheduled by the MOH. Data collectors should be given copies of letters of introduction that confirm their identity and authorization to survey that site. Study investigators should develop a system for collecting, grouping, and storing completed data collection forms.

Troubleshooting

Drug Availability Study Troubleshooting

As mentioned earlier, the key to successful data collection is good planning. However, no matter how thorough the planning, problems can always arise. Such unexpected problems can be minimized if good, open communication among study team members is maintained, and all participants remain flexible and willing to adapt to new situations. Table 10 presents a few typical problems, along with suggested solutions, that can happen while conducting the Drug Availability Study. However, remember these examples are only illustrative. Every country is different and can present the investigator with different, country-specific problems.

Table 10. Illustrative Examples of Potential Problems and Possible Solutions in Drug Availability Studies

Potential Problems	Possible Solutions
Key informants do not keep scheduled appointments.	Reconfirm meeting times, clinic hours, and retail outlet hours. Create backup options and, if possible, try to schedule meetings in the same geographic area on the same day.
Data collectors do not show up for training and work.	Recruit a few extra data collectors to anticipate any transportation or personal emergencies among data collectors. Also, pairing data collectors into teams will ensure having a backup option.
DMM antimalarial drugs are not available in the country.	As mentioned in Chapter 2, the study team should adapt the sample list of DMM antimalarial drugs (Table 6) to the country setting. If a product on the list is not available, select the best alternative available in-country.

Potential Problems	Possible Solutions
The dosage form of the drug is different than indicated on the sample data collection form.	The sample data collection forms should also be adapted and tested as outlined in Chapter 2. This step should catch any inconsistencies before the data collection begins.
Health facility and drug retail managers are skeptical or resistant to permitting someone to go through confidential patient records.	Sometimes having an "official government letter of authorization" may not be enough to gain cooperation of managers. Try to gain support for the study from health professional groups such as associations for doctors or pharmacists. Also talk to the managers about the study and the ultimate benefit to the country. Emphasize that you are not evaluating the health staff personally or that specific health facility, but that instead you are trying to assess how well the health system as a whole is functioning as regards malaria drug management.
A sample facility is closed or not functioning for some reason.	Have a defined "substitute" list of facilities in anticipation of any closings. Data collectors should not be left to make the decision on their own about selecting sites.
Data collectors are not completing the data forms correctly and some are not legible.	Make sure that the data collectors use pens, not pencils, to fill out the data collection forms. Conduct spot checks of the forms to catch any problems early in the process and make pay contingent upon receiving acceptable forms.

Drug Use Study Troubleshooting

The Drug Use Study requires the investigators to manage a number of different activities and, as such, there may be times when problems arise. Remind study team members to remain flexible; they must be ready and willing to adapt to new situations. Many of these problems may be unforeseen, but many of them can be minimized by good planning. Table 11 presents a few typical problems, along with suggested solutions, that can happen while conducting the Drug Use Study. These examples are only illustrative. Every country is different and can present the investigator with different, country-specific problems.

Table 11. Illustrative Examples of Potential Problems and Possible Solutions in Drug Use Studies

Potential Problems	Possible Solutions
Fewer than 30 medical records exist for malaria.	Collect as many records as available and build in a process of either asking the team leader for advice or going to a predetermined backup facility
The specific diagnosis is not on the medical records.	Before beginning the review of patient records, the study team should meet with health facility managers and health workers to define a list of local terms or symptoms that are equivalent to malaria. This should be part of the process for testing the data instruments and methodology. The team should develop (and reach consensus) on a master list of possible symptoms that can be used to describe malaria. The list can help identify patient encounters for malaria.
In rural areas, insufficient numbers of drug retail outlets are near the sampled health facility.	Use proportional sampling so that more sampled drug retail outlets are concentrated in urban areas.
Health facility managers are skeptical, or they resist the idea of someone observing medical consultations.	Sometimes having an "official government letter of authorization" may not be enough to gain the cooperation of managers. Also, talk to the managers about the study and point out its ultimate benefit to the country. Assure the manager that neither the names of staff nor patients will be used on the data forms and that the information collected will be shared with them.
Local drug retail outlet community has identified a data collector as a simulated purchaser.	Data collectors should do the simulated purchases as quickly as possible after they arrive in a particular geographic area. However, if word still gets out that surveyors are in town, change the time (or other logistics pattern) for purchases to be made, or switch the list of outlets with a team member.

Potential Problems	Possible Solutions
Data collectors do not have enough money to make the simulated purchases.	As part of testing the data instruments and the simulated purchases scenarios, estimate the cost of local products in drug retail outlets and factor the cost into the budget for local expenses by data collectors. Build in a process to reimburse data collectors for purchases that exceed the estimate. Make sure that reimbursement is contingent upon returning with the products and the receipt.
Prescribed drugs are recorded by brand names that are unfamiliar to the data collectors.	Information should be written on the data forms exactly as written in the patient encounter record, even if the terms are unfamiliar to the data collector. Data collectors should be instructed to avoid any interpretation.
Prescribed drugs are identified, but numbers of units are not.	The data needed for a particular patient encounter may not be in the same record source. Start with the patient register and then move to the medical records. If drug data are still missing, see if the facility has pharmacy or dispensing records. If all else fails, ask the staff, during the completion of the medical personnel questionnaire, how many units of each drug they would normally provide for a child of that age, with the symptom(s) listed in the record. Then write this information on the form, but draw a circle around it. The circle means that information missing from the record came from an interview.
Data collectors are not completing the data forms correctly and some are not legible.	Make sure that the data collectors use pens, not pencils, to fill out the data collection forms. Conduct spot checks of the forms to catch any problems early in the process and make pay contingent upon receiving acceptable forms.

Record Data

It is important to instruct data collectors to write legibly with a pen (not pencil) and to use marks or phrases that indicate a complete thought or response when filling out the data collection instruments. Depending on the data collection instrument, the collector may need to use a check mark, write "*YES*" or "*NO*," circle a response, or write a phrase or sentence to explain a particular

finding. Careful marking is important because the person completing the form may not be the same person who will enter the data or tabulate the results.

Someone on the study team, usually the data collection team manager, should be designated to review each data collection instrument when it is completed, to check the data for completeness and correctness. **This process is useful because it will allow identification of any problems early in the data collection phase, and corrective interventions can be implemented to avoid future mistakes.**

To avoid confusion, it is advisable to collate and prepare data for analysis as the data are collected. The most efficient approach for data entry is to identify experienced data entry clerks to do the data entry. While this represents an additional expense, it is more cost-effective over time. The data entry person should be instructed to put his or her initials on each data collection form in a designated spot to indicate that the data entry is completed for that form.

Completing the Data Collection Instruments

At the end of each site visit, every data collection questionnaire, checklist, or form completed during the visit should be examined for incomplete data. The responsible data collector should make every attempt to collect the incomplete data before leaving the site.

Before beginning the process to derive the specific indicators, a complete recheck and editing are necessary to clean the data. If data for a particular item on the data collection form are missing or incomplete, that item (not the entire data collection form) should be eliminated. The number of eliminated items should be counted and discussed in the final report

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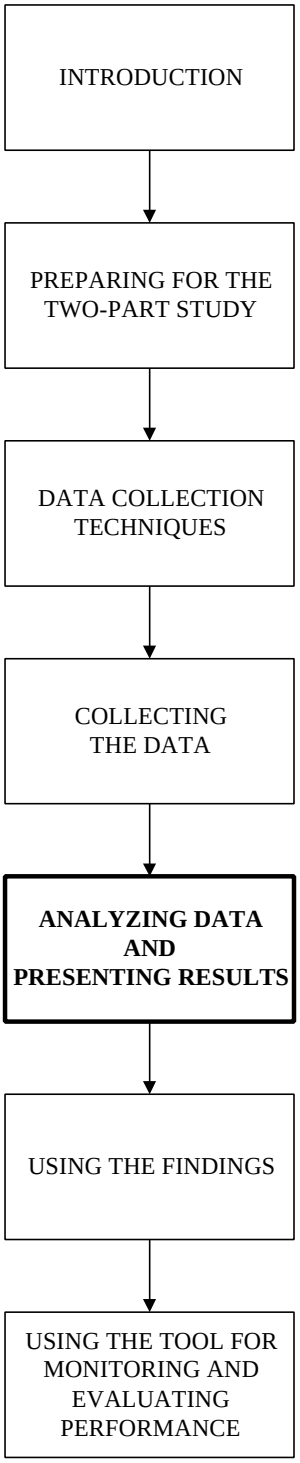
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Chapter 5.

ANALYZING DATA AND PRESENTING RESULTS

Now that the data have been collected, the next step is the analysis. Analyzing the data will help to identify strengths and weaknesses in the drug management process and highlight areas that need specific action to improve malaria drug management capabilities. Analysis should proceed in a systematic fashion by (1) calculating the indicators and summarizing the information; (2) interpreting the results; (3) discussing the findings; and (4) preparing a written report.

Calculating the Indicators and Summarizing the Information

Once the data have been collected, the results for each specific indicator can be derived manually from the appropriate data collection instrument. Annex 1 of this manual provides specific instructions and examples on how to calculate each indicator. Alternatively, the following computerized methods could be used for collating the survey results and deriving the indicators:

- Spreadsheet
- Database
- EPI Info

The instructions and examples in Annex 1 provide the information needed to design the structure of the computerized tool chosen. Some thought should be given to how the data should be grouped or summarized. It is important to distill the large volume of data into a few key findings that capture the study results. Summarize the data by indicator, noting subgroupings that may be useful to the analysis, such as geographic region, type of health facility, and/or target audience. Once the data are summarized, they will be easier to review and analyze.

Interpreting the Results

At the end of the fieldwork and prior to the implementation of a particular intervention, it is important to spend time as a team to interpret the findings. No matter how well the assessment was designed and planned, the data obtained may not be totally reliable, for any number of reasons. Part of the job of the study team when analyzing data is to determine what biases, inaccuracies, or inconsistencies may exist, and what precautions are necessary in interpreting the results. Problems encountered while collecting the data should be recorded on the data collection forms in the space provided for this.

Researchers and study team members should all play an active role in examining data and considering what type of additional analyses may be appropriate. One strategy is to hold a synthesis meeting of everyone involved in the investigation. If not everyone at the meeting is familiar with all aspects of the data collection, the first activity should be to present separate reports on each study. The reports should be brief and cover the specific study questions addressed, methods used, results, and conclusions. Written summaries of findings, along with tables and graphs should be distributed. Through the analysis, specific drug management problems will become more apparent, as will the group of prescribers or patients most likely to gain the most from an intervention. On the basis of this understanding of the problems to be addressed, the synthesis group should then direct its attention to designing an intervention.

Tables 12 and 13 present the DMM indicators for the Drug Availability and Use Studies, their interpretation, and the potential actions that can be taken as next steps. It is important to understand that none of the DMM indicators should be viewed in isolation or taken at face value. It is the complete set of indicators that helps to give a meaningful picture of the drug management situation. The results become even more indicative when they can be compared to a baseline over time.

Table 12. Interpretation of Indicators for Drug Availability Study

Indicator Name	Desired Change over Time	Interpretation	Identification of Underlying Problems and Potential Actions
1. Percentage of median international price paid for a set of DMM tracer drugs that was part of the last regular MOH procurement	Decrease	The result for each antimalarial drug should be reviewed. The higher the percentage, the greater the potential cost savings. The goal should be for the MOH to achieve at least or better than a 1:1 ratio when the MOH procurement price is compared to the international price.	Examine all factors that contribute to the MOH procurement price before deciding on possible interventions. Possible areas to review include the terms of tender, amounts ordered and potential economies of scale, and supplier prices for each drug. For health facilities in decentralized settings, compare prices through local private sector procurement vs. prices through regional or national warehouses. If revolving drug funds are used, compare the sales price of MOH health facilities to sales price in drug retail outlets.
2. Average percentage of a set of unexpired DMM antimalarial drugs available in (a) MOH storage and health facilities and (b) retail drug outlets	Increase	Theoretically, all, or 100%, of the drugs should be available, all of the time. However, this indicator only provides a snapshot of the availability of drugs for malaria at the time of the study.	To determine why availability is low requires further analysis. For example, problems could be in the area of budgeting, theft, wastage, quantification, delivery problems, and/or inventory management. Once the specific causes have been identified, potential interventions can be developed.
3. Average percentage of time out of stock for a set of DMM antimalarial drugs in MOH storage and health facilities	Decrease	The target for this indicator should be 0%, or no stock- outs. The result of the data collection will help to understand if availability is constant over time.	For high percentages of stock-outs, investigate to determine where the breakdown is in the system. Check for seasonal variations, changes in stock levels that correlate with procurement activities, etc.

Indicator Name	Desired Change over Time	Interpretation	Identification of Underlying Problems and Potential Actions
4. Average percentage of stock records that corresponds with physical counts for a set of DMM antimalarial drugs in MOH storage and health facilities	Increase	This measures the quality of the stock record-keeping system. Caution: Some facilities update records periodically rather than on an ongoing basis. Study investigators should consider this when reviewing the accuracy of the record-keeping system.	A low percentage of correspondence may suggest a need to review the record-keeping system. Training may be needed in math skills, stock record keeping, and/or inventory procedures.

Table 13. Interpretation of Indicators for Drug Use Study

Indicator Name	Desired Change Over Time	Interpretation	Identification of Underlying Problems and Potential Actions
5. Percentage of MOH health facilities visited with an official manual of treatment guidelines for malaria	Increase	Theoretically, all, or 100%, of facilities should have an official copy of treatment guidelines. Although the presence of guidelines does not mean that staff use them, and they do not ensure rational prescribing, treatment guidelines do provide a reference source that supports more appropriate prescribing.	Identify resources to provide at least one copy of treatment guidelines per facility. Distribution of the guidelines should be accompanied by training in the use of the guidelines.
6. Percentage of encounters diagnosed as uncomplicated malaria that are prescribed antimalarials consistent with treatment guidelines	Increase	This indicator measures adherence to malaria treatment guidelines. High percentages identify a positive behavior that should be reinforced or encouraged. Low percentages identify the need for improvement.	For low percentages, investigate to determine why the behavior exists and which factors contribute to the behavior. Then, design appropriate interventions to correct the behavior.
7. Percentage of encounters with patients diagnosed with uncomplicated malaria that are prescribed quantities of appropriate antimalarials sufficient to complete a full course of treatment	Increase	This indicator measures adherence to malaria treatment guidelines. High percentages identify a positive behavior that should be reinforced or encouraged. Low percentages identify the need for improvement. Low percentages could indicate that the patient does not complete a course of treatment. This behavior could have potentially serious consequences for the patient as well as contributing toward drug resistance.	For low percentages, investigate to determine why the behavior exists and which factors contribute to the behavior. Then, design appropriate interventions to correct the behavior.

Indicator Name	Desired Change Over Time	Interpretation	Identification of Underlying Problems and Potential Actions
8. Percentage of prescribed antimalarial drugs actually dispensed by public health facilities	Increase	Theoretically, all, or 100%, of drugs prescribed should be dispensed. Low percentages identify problems of availability or poor dispensing practices.	Investigate to determine specific reasons why prescriptions presented for dispensing are not filled with the prescribed drug. The most common reasons are that the drugs are not affordable to the patient/caregiver and the drugs are not available.
9. Percentage of cases where the quantity of antimalarial drugs dispensed by public health facilities was sufficient to complete a course of treatment	Increase	Theoretically the drugs dispensed should be enough to complete the course of treatment. Low percentages identify problems of availability or poor dispensing practices. These difficulties will discourage the patient from completing the full course of treatment and so add to the problem of drug resistance.	Investigate to determine specific reasons why drugs are not dispensed in sufficient quantities for the full course. The most common reasons are that the drugs are not affordable to the patient/caregiver and the drugs are not available.
10. Average cost of drugs prescribed as a percentage of costs if STG norms for treatment were followed	Increase or Decrease	If malaria guidelines are followed, then costs should be as expected. Any deviation suggests possible prescribing practices different from recommended treatment norms. Cost differences may indicate inappropriate prescribing and should be investigated for prescribing practices not in line with official guidelines.	For large differences, investigate to determine what the differences are and why they exist. Once specific practice is identified, interventions can be designed to address the problem.
11. Percentage of caregivers who could correctly describe how to give the prescribed medication	Increase	Low percentage indicates that health workers or drug dispensers are not providing enough information to patients about the medication, which can lead to nonadherence and treatment failure.	Identify the specific communication problems and investigate the usefulness of alternative communication strategies such as the use of local language, pictograms, demonstrations, etc.

Indicator Name	Desired Change Over Time	Interpretation	Identification of Underlying Problems and Potential Actions
12. Percentage of health workers who provided [some] information to patient/caregivers on how to give the recommended drug(s)	Increase	This indicator, together with 11, can help pinpoint communication problems between the health worker and the patients/caregivers. A low percentage indicates that health workers are not providing enough information to patients/caregivers about the medication, which could be a reason for nonadherence to treatment.	Investigate the problem to determine why practitioners are not following the guidelines. Malaria training may need to be reinforced to improve communication between the health worker and the patient/caregiver.
Supplemental Indicator			
13. Percentage of encounters with pregnant women living in endemic areas who are prescribed an appropriate antimalarial prophylaxis at antenatal clinics	Increase	This indicator measures adherence to malaria treatment guidelines. High percentages identify a positive behavior that should be reinforced or encouraged. Low percentages identify the need for improvement.	For low percentages, investigate to determine why the behavior exists and which factors contribute to the behavior. Then, design appropriate interventions to correct the behavior.

Discussing the Findings

Until now, only the few people involved in the data collection process have been aware of the study findings. Now, health facility managers, MOH representatives, and others need to have an opportunity to be informed. There should be a formal presentation, encouraging in-depth discussions about the meaning of the results, specific drug management concerns, and potential interventions.

Those deciding how to present the findings should take into consideration both the intended audience and what specific results the audience should understand by looking at the findings. When presenting the findings, give equal attention to both strengths and weaknesses. The goal of the presentation is to determine a course of action for building on the strengths and for increasing capabilities in the weaker drug management areas.

When developing presentations for policy makers, it is advisable to present a very clear executive summary and to the extent possible, present key findings, recommendations, and projections of impact. Usually, these presentations are best achieved graphically and in text or table form. Visual presentations of data in the form of tables, graphs, pie charts, and so forth work best, supported by the written report to explain details. Annex 2 includes a sample table for presenting the indicator data.

The presentation should provide an overview of the goals and objectives of the drug management study, the process undertaken, and the major indicators measured. This information will help people to understand how the conclusions were reached. Emphasize how current drug management practices affect the ability of the Malaria Program Managers to achieve goals and to improve staff performance and the quality of services. The session can lead to increased support for improvement in prioritized areas, reinforcing the audience's understanding of the need for and interest in improving drug management for malaria.

Preparing a Written Report

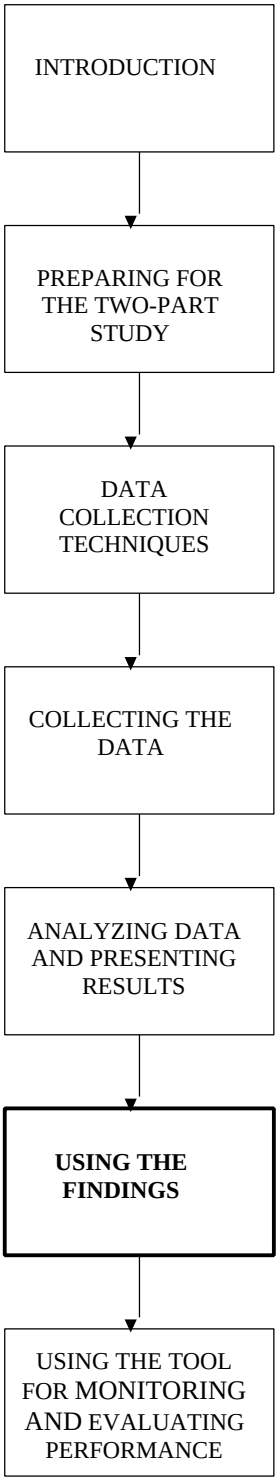
A written report should be prepared to document the data collection experience and the findings. At a minimum, the report should include indicator tables, a list of the drugs most often prescribed, observations made during data review, survey background, and the different methodologies used to collect the data. In general, the report should include the following sections:

Executive Summary	Present key findings, recommendations, and projections of impact.
Introduction	Summarize the study objectives, the scope of the study, and the outline of the way the report is presented.

Methods	Summarize the indicator-based approach, the data collection techniques, instruments, sites, the sampling process, personnel, fieldwork organization and supervision, and mode of data analysis.
Findings	Tabulate and describe the study results that include identification of the strengths and weaknesses of the drug management system. Also, discuss any assumptions, biases, inaccuracies, or inconsistencies that may exist, and what precautions are necessary in interpreting the data.
Discussion	Address the problems encountered in conducting the study and possible underlying reasons and explanations for the main findings.
Conclusion	Present inferences, recommendations for corrective actions, and likely follow-up interventions.

A copy of the written report should be presented to the MOH Malaria Program Manager. The report, along with the recommendations for follow-up interventions, will provide the necessary documentation that can help to support the need for system improvements.

DRUG MANAGEMENT FOR MALARIA MANUAL



Chapter 6.

USING THE FINDINGS

Responding to the DMM indicator results and other assessment findings requires a well-thought-out approach for selecting and implementing the most appropriate interventions to address malaria drug management problems. Before attempting to improve drug availability or change drug use, the scale of the problem should be assessed and quantified (see Chapter 5). The underlying reasons for the problem then need to be investigated. Intervening before understanding the reasons for a drug shortage or a problem with prescribing practices can lead to unintended and negative consequences.

Developing an intervention strategy involves six major steps. These include the following:

1. Identify the problem and recognize the need for action.
2. Identify underlying causes and motivating factors.
3. List possible interventions.
4. Assess resources available for action.
5. Choose an intervention to test.
6. Monitor the impact and restructure the intervention.

The DMM indicators have been developed to measure key aspects of the drug management system, in both the public and private sectors, and they should be viewed as the *first step* of an investigation. Conducting the DMM studies should also reveal specific problems that may be addressed, but the studies may not provide enough information on the underlying causes and motivating factors that contribute to the problems. Therefore, each problem identified should be examined individually to ensure an in-depth understanding of the cause. Probing for a more in-depth understanding of a particular problem may require supplementing the findings with

structured interviews or small focus groups. The information from the follow-up studies can be used to design interventions.

For example, some problems may be due to the national or regional drug management system and not specifically related to malaria. This situation is especially likely for the availability portion of the assessment. In such cases, the data developed through the assessment will be significant in documenting the negative effects of such policies or procedures on the management of malaria. In addition, it may be that one intervention approach could solve more than one problem. But in order to monitor for specific improvements, as discussed later, it is important to have a clear perspective of what the intervention is intended to do, problem by problem.

Following is a brief listing of some of the more common problems encountered in drug management. Each problem statement is followed by a summary of key points that should be considered when developing an appropriate response. This list is not exhaustive and is only meant to be illustrative. On the contrary, many problems may be unique to a specific country or region and thus require a unique solution. Selecting and implementing interventions requires time, teamwork, and commitment. The time spent in the planning and coordination phase will help ensure a successful outcome.

Drug Availability

Procurement

An effective procurement process ensures the availability of the right drugs in the right quantities, at reasonable prices, and at recognized standards of quality. Effective procurement is a collaborative process between the procurement office and technical and policy officials.

***Problem*:** Too many drugs are on the procurement list.

Key Points: Virtually no health program can afford to purchase all drugs on the market. A limited drug list or formulary, defining which drugs for malaria will be purchased, is one of the most effective ways to control procurement costs. It simplifies other supply management activities and reduces inventory holding costs as well.

Possible Response: The first step is to order all drugs for malaria by generic name, and the second step is to avoid generic duplication by ordering only one brand or label of each generic product. Another option for reducing the procurement list is to limit the purchase of therapeutically similar drugs by restricting the essential drugs list or drug formulary to one of these drugs and combining the estimated purchase volume into a single, much larger quantity of the drug selected to take advantage of economies of scale.

The health system needs to be prepared to counter resistance from some doctors, who prefer a wide range of choices, and from drug suppliers, whose products may be removed from the

list. Resistance can often be overcome by documenting the cost savings possible (through the use of indicators) with the restricted procurement list and by pointing out the benefits of year-round access to the limited list rather than sporadic access to a larger list of drugs.

***Problem*:** There is too much stock of some drugs and not enough of others.

Key Points: Accurate estimates of drug requirements are needed to avoid stock-outs of some drugs and overstocks of others. One way to quantify pharmaceutical needs is to start with accurate past consumption data from all units being supplied. Unfortunately, in many countries, consumption data are incomplete or do not reflect real need because the supply pipeline has never been full.

Another method to estimate drug requirements is to base the estimate on morbidity data (e.g., the frequency of illness). The morbidity method estimates the need for specific items based on the expected number of visits to a clinic, the incidence of common diseases, and standard treatment guidelines for the diseases considered. This method requires data on the service population, accurate clinic visits data, and use of the malaria Standard Treatment Guidelines for the target conditions.

The issue of multiple drug sources complicates the problem of stock management even more. For example, in many countries, some drugs are procured centrally by the MOH, others are donated by international organizations, and still others are procured from the regional or district level independent from the central MOH.

Possible Response: Expert technical assistance in how to quantify drug needs for malaria may be useful in the initial phases of the procurement program, with local officials participating to gain an understanding of the methodology. Also, arranging meetings with the major donor organizations to discuss donor coordination for drug procurement can improve the management of drug supply.

***Problem*:** Financing mechanisms cause problems with the procurement cycle.

Key Points: Inventory management improves when drugs can be ordered when needed rather than at an arbitrary point in the government fiscal year. When suppliers know that orders will be placed promptly after tendering and that payment will be made upon delivery, prices will be much more competitive.
Possible Response: Decoupling the drug procurement cycle from the government budget cycle has substantial management advantages. Strategies such as decentralized financial management and revolving drug funds are increasingly being employed to separate drug procurement from the annual MOH budget cycle. This separation also usually requires some form of cost recovery, such as revolving drug funds.

Alternative systems for supplying drugs to the public health systems include the central medical stores (CMS) system,[7] autonomous supply agency system,[8] direct delivery system,[9]

[7]Conventional drug supply system in which drugs are procured and distributed by a centralized government unit.

prime vendor system,[10] and private pharmacy system.[11] Whichever system is used, checks and balances must be put in place for all major procurements and involve the procurement officer, health practitioners, and other user representatives.

Inventory Management

***Problem*:** Stock records are poor.

Key Points: Accurate and current stock records are essential to good inventory management. Stock records are a key source of information used to calculate needs. Thus, inaccurate records will produce inaccurate needs estimations (and problems with stock-outs, leaks, and expiry).

Possible Response: Each inventory system should monitor performance with indicators and produce regular reports on inventory and order status, operating costs, and consumption patterns. Staff training may be necessary as part of the plan to improve inventory management, such as the WHO/BASICS Drug Supply Management Training Workshop for First-Level Facilities or the International Dispensary Association (IDA)/Management Sciences for Health (MSH) Managing Drug Supply for Primary Health Care Course for middle to higher level facilities.

***Problem*:** Inadequate quantities of drugs are in storage.

Key Points: The primary reason for holding stock in a drug supply system is to ensure availability of essential items at all times.

Possible Response: The selection of malaria items to stock should be based on their value to the treatment of the disease and on the regularity and volume of consumption. VEN (vital, essential, nonessential) and ABC analyses are useful tools for defining which malaria products on the essential drugs or formulary list must be held in stock. Most of the drugs for malaria should be promoted as vital (V) and, therefore, should always be available. Whichever formulas are used, it is necessary to adjust purchase quantities to take into account factors such as seasonal demand, disease patterns, expected changes in utilization or prices, currency fluctuations, and availability of storage space. One possible source for information on how to use ABC and VEN analysis is MSH's book, *Managing Drug Supply: The Selection, Procurement, Distribution, and Use of Pharmaceuticals in Primary Health Care*.

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[8]An alternative to the CMS managed by an autonomous drug supply agency.

[9]A decentralized, non-CMS system in which drugs are delivered directly to districts and health facilities by suppliers following government procurement.

[10]Government establishes a storage and distribution contract with a single company that is contracted to manage distribution to districts and health facilities. Suppliers deliver drugs and supplies directly to the prime vendor.

[11]Drugs are provided by private pharmacies in or near government health facilities.

Distribution

***Problem*:** The drug distribution system is unreliable.

Key Points: Drug distribution systems in some developing countries are constantly challenged by such problems as the lack of money for fuel, bad roads, union strikes, and so on. A well-run distribution system should maintain a constant supply of drugs, keep drugs in good condition, minimize drug losses caused by spoilage and expiry, minimize drug shortage points, use available transport as effectively as possible, reduce theft and fraud, and provide information for forecasting drug needs.

Possible Response: There should be a program of performance monitoring to ensure that the distribution system works as intended. Senior managers should regularly monitor the cost and performance of the distribution system as important indicators of the health system's operations. In some countries, private or parastatal distribution companies can provide cost-effective alternatives for the storage and distribution of drugs, especially at the national and regional levels. Major alterations in the system should be introduced only after careful evaluation and planning, taking into account available human, financial, and material resources.

Drug Use

***Problem*:** Antimalarials are used inappropriately.

Key Points: This could cover a number of problems such as overuse of chloroquine in resistant areas and noncompletion of a full course of treatment.
Possible Response: Training is the most common intervention implemented in response to inappropriate prescribing practices. Training can be conducted in many different ways with a broad range of objectives. In general, training interventions targeting health providers are most successful when the training does the following:

- Is problem-oriented and focuses on a single health problem or practice at a time
- Incorporates multiple training approaches (e.g., lectures, group problem solving, roleplaying, opportunity to practice skills)
- Provides training at the work site
- Uses opinion leaders or district-level staff as trainers
- Involves practical skills orientation
- Provides multiple sessions over time

In addition, training interventions can be reinforced through the use of incentives and messages intensified through concurrent community and health worker education, supervision, and drug supply management. For example, WHO recommends that the "*messages should promote appropriate use of antimalarials through clear, concise, and culturally appropriate messages...*" channeled through "*existing channels of community*

communication .... such as religious organizations, NGO's, community leaders, and other social structures."[12]

***Problem*:** Drug treatment costs are high.

Key Points: One of the basic tenets for promoting good drug management practices for malaria is that the use of standardized treatment guidelines, if followed, will provide cost-effective, appropriate care that is likely to be cheaper than the cost of care if guidelines are not followed. Factors contributing to the high cost of drug treatment include the unnecessary prescribing of multiple drugs, overprescribing of injections, and prescribing of brand-name products rather than generics. Also, because many consumers hold the belief that public health facilities have limited stocks of drugs, some consumers bypass the health facility and go directly to private-sector drug sellers for drug treatment, choosing the likelihood of greater availability in spite of probable higher costs.

Possible Response: As mentioned earlier, developing a limited drug list or formulary is one of the most effective ways to control drug costs. Promoting the use of generic drugs over brandname products and monitoring prescribing practices for inappropriate use of antimalarials and instances of polypharmacy can also help to gain control over drug costs.

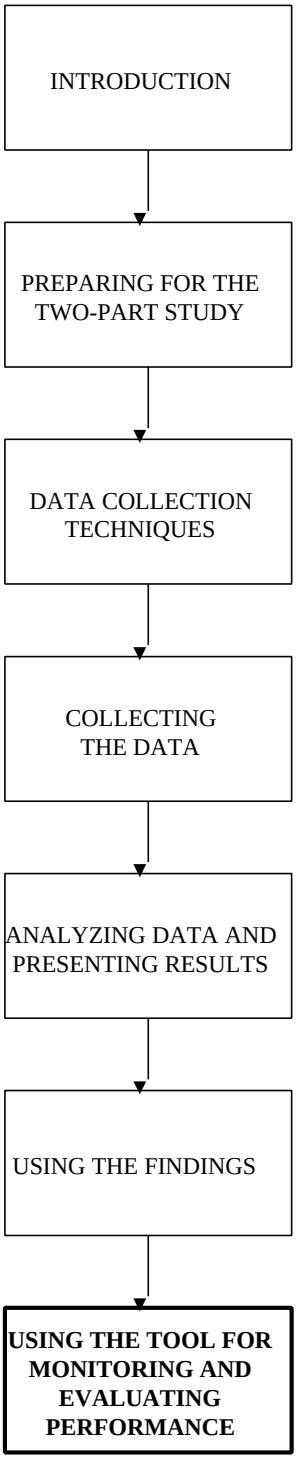
***Problem*:** Standard treatment guidelines are not followed.

Key Points: Standard treatment guidelines help practitioners or prescribers make decisions about appropriate treatments for specific clinical conditions. Standard guidelines, together with an essential drugs list, are powerful tools to promote rational drug use. They can also assist in the standardization of prescribing patterns. The treatment guidelines should include only those drugs for malaria on the essential drugs list. This limitation will ensure that the supply system, based on the list of essential drugs, supports the treatment guidelines.

Possible Response: First, make sure that each facility has an official copy of the standard treatment guidelines. Group commitment to standards by the staff at a health facility or continuing involvement in peer monitoring may motivate and sustain change. Routine supervision and monitoring using indicators or simple protocols, as well as monthly audit and feedback of performance indicators, can be effective for improving specific practices. The reasons for clinically inappropriate drug use practices may be quite complex and multifactoral, including perceived patient demand, cultural misconceptions about drugs, prescribers' limited clinical experience, and the promotion practices of drug representatives. Such practices can also contribute to higher costs.

Drug use interventions should generally be targeted to improving a few specific aspects of drug use. In addition, program managers should involve researchers in the design and implementation of national programs to strengthen and better evaluate the programs' impacts on quality use of medicines.

[12] WHO, Malaria Programme DDC Division, Harare, Zimbabwe. May 1999. Framework for developing, implementing and updating antimalarial drug policy in Africa: A guide for country malaria control programmes, Draft 17: 4.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Chapter 7.

USING THE TOOL FOR MONITORING AND EVALUATING PERFORMANCE

Once the DMM assessment has been completed and the data analyzed, the findings can represent a source of quantifiable baseline measures. Having baseline measures is critical to monitoring the impact, negative or positive, of any intervention.

It is important to monitor drug availability and use as a way to evaluate the efficacy of an intervention. To determine if adequate progress is being achieved, it is necessary to know what is expected. Interventions should be evaluated by looking for both intended and unintended changes in specific outcomes. For example, an intervention changing the first-line antimalarial from chloroquine to sulphadoxine-pyrimethamine (SP) may affect the usefulness of other sulfa drugs such as chlorproguanil dapsone (LAPDAP). Similarly, introducing SP as a first-line drug in areas with a high incidence of human immunodeficiency virus (HIV) infection may result in a higher rate of side effects from taking SP.

The DMM indicators can be used to supervise and monitor performance. In selecting indicators for monitoring, it is important to consider how the data will be collected. Data for some indicators may be routinely available from standard recording and reporting systems (such as percentage of DMM antimalarial drugs available), whereas data for other indicators may require a special survey (such as for the percentage of stock records that correspond with physical counts). Thus, the sources and the costs of collecting and processing these data must be carefully considered in selecting indicators to monitor.

There are a few potential problems that can develop when using indicators for monitoring. Such problems include failure to take action based on findings; overambitiousness (using too many indicators); failure to focus on key questions; selecting indicators that are too complex; lack of integration with work planning; failure to build on existing information; and lack of objectivity. Collecting data on a few specific indicators on a quarterly or semiannual basis should be a key management strategy to measure progress toward improvements in malaria drug availability and use. By comparing indicator values among districts and among health facilities, it should be possible to measure the impact of an intervention over time and better identify areas of concern that warrant further action.

Once an intervention has been identified, performance targets should be established. A performance target is a desirable and, in principle, attainable standard of practice. The DMM indicators can be used to measure the extent to which the targets and objectives of an intervention are being attained. For example, the indicator may be the percentage of DMM antimalarial drugs in stock, and the performance target may be 80 percent availability at each level for this list of drugs. Performance targets should be set for each indicator.

When choosing the most useful outcomes to measure, consider the following:

- Select outcomes that can be clearly and explicitly defined.
- Select outcomes that can be reliably measured by the indicator, preferably using routinely collected data.
- Focus on a few important outcomes rather than measuring all possible changes.
- Select the key behaviors targeted by the intervention and the most likely substitute behaviors.
- Measure more than one dimension of success, especially if some changes are secondary—for example, changes in prescribing that follow changes in knowledge about resistance to specific antimalarial drugs.
- Decide how often to monitor.
- Budget for human and financial resources needed for monitoring.
- Disseminate the results.

There are no universal targets of “acceptable” performance. Each country is unique, and setting performance targets will depend on many factors, such as the time frame of the intervention, the human and economic resources available, national policies, and the level of decentralization, to name just a few. Most important, however, is that targets should be established based on agreed-upon standards of performance and according to the local situation.

Following is a list of suggested DMM indicators that can serve to monitor performance, particularly at the health facility level. The performance target (included only for illustrative purposes) is noted in parentheses following the indicator.

Availability

2. Average percentage of a set of unexpired DMM antimalarial drugs available in (a) MOH storage and health facilities and (b) retail drug outlets (90%)

3. Average percentage of time out of stock for a set of DMM antimalarial drugs in MOH storage and health facilities (10%)

4. Average percentage of stock records that correspond with physical counts for a set of DMM antimalarial drugs in MOH storage and health facilities (90%)

Use

6. Percentage of encounters with patients diagnosed with uncomplicated malaria that are prescribed an antimalarial consistent with treatment guidelines (90%)

10. Average cost of drugs prescribed as a percentage of costs if STG norms for treatment were followed (±10%)

11. Percentage of patients/caregivers who could correctly describe how to take/give the prescribed medication (90%)

A well-designed monitoring system can usually provide information on what happened or what did not happen. Managers should always check to see whether the information has been used, how it has been used, and what action has been taken.

No monitoring system is complete without feedback. Giving feedback to individual units or staff members tells them how well the reporting has been done and how useful the information is. Feedback also demonstrates the value and importance of reports. As such, it represents one of the most powerful tools for motivating staff.

ANNEXES

ANNEX 1. DMM INDICATORS

DMM INDICATORS

List of DMM Indicators

Following is the list of 13 DMM indicators that will be used to assess the availability and use of antimalarial drugs for the treatment of malaria. The list includes four availability indicators, seven drug use indicators, one observation indicator, and one supplemental indicator.

Drug Availability Study Indicators

1. Percentage of median international price paid for a set of DMM antimalarial drugs that was part of the last regular MOH procurement

2. Average percentage of a set of unexpired DMM antimalarial drugs available in (a) MOH storage and health facilities and (b) retail drug outlets

3. Average percentage of time out of stock for a set of DMM antimalarial drugs in MOH storage and health facilities

4. Average percentage of stock records that correspond with physical counts for a set of DMM antimalarial drugs in MOH storage and health facilities

Drug Use Study Indicators

5. Percentage of MOH health facilities visited that had a copy of official treatment guidelines for malaria

6. Percentage of encounters with patients diagnosed with uncomplicated malaria who are prescribed an antimalarial consistent with treatment guidelines

7. Percentage of encounters with patients diagnosed with uncomplicated malaria who are prescribed quantities of appropriate antimalarials sufficient to complete a full course of treatment

8. Percentage of prescribed antimalarial drugs actually dispensed by public health facilities

9. Percentage of cases where the quantity of antimalarial drugs dispensed by public health facilities was sufficient to complete a course of treatment

10. Average cost of drugs prescribed as a percentage of costs if STG norms for treatment were followed

11. Percentage of patients/caregivers who could correctly describe how to give the prescribed antimalarial medication

12. Percentage of health workers and drug retail outlets that provided [some] information to patients/caregivers on how to give the recommended drug(s)

Supplemental Indicator

13. Percentage of encounters with pregnant women living in endemic areas who are prescribed appropriate antimalarial prophylaxis at antenatal clinics

Indicators Description Format

This section presents detailed descriptions for each DMM indicator. Each description follows exactly the same format, which is summarized below.

Indicator data can be collected at four different levels of the health care system. Each indicator in the descriptions that follow is coded according to the level at which it is measured, with the code appearing in parentheses after the indicator title. The health system level codes used are—

- **C** Central level: under direct supervision of the central government
- **R** Regional or district level: acts as the intermediary; provides supplies to the health facilities and not directly to patients
- **F** Health facility level: provides direct care to the patient population
- **D** Drug retail outlet level: usually serves as the patient's primary private sector source for drugs

Indicator Name: The name of the indicator, along with the different system levels that may be examined (for example, **C/R/F** signals that the indicator may be applied at the central, regional, and health facility levels).

Rationale: The reason that the indicator is important.

Definition: The meaning of the indicator and the terms used to describe the indicator.

Data Collection: The most likely source(s) of information is summarized in a table indicating *where* the data are to be collected, *whom* to ask for assistance, and *what* documents and records to review.

Brief discussions of methods and issues related to data collection.

Citations of the data collection forms to be used, if any.

Computation & Example: Computations, if any are needed, are accompanied by an example using illustrative data.

Presentation: Brief example of how results may be presented.

Notes: Suggestions for additional information or discussion required to put the indicator in proper context or to provide more detail.

Drug Availability Study Indicators

An accurate and systematic assessment of the logistics supply system is a prerequisite for planning improvements to the malaria drug supply system. The DAS indicators (1 through 4) focus on procurement and distribution of antimalarials.

The most important methods for collecting information for this availability study are likely to be document review, key informant interviews, and physical inventory checks. Data collection sites will include MOH central offices, central and regional medical stores, and health facilities. The findings of the study will be useful to identify specific problems in the system, plan corrective interventions, monitor progress, and compare the performance of one system with another.

1. Percentage of median international price paid for a set of DMM antimalarial drugs that was part of the last regular MOH procurement (C/R/F)

Rationale: This indicator will help determine the potential savings to the MOH that could be achieved if procurement practices are improved and, in this way, supports changes in the pharmaceutical supply system.

Definition: Median international price is the median free on board (FOB) price from a set of international suppliers, adjusted to reflect estimated CIF[13] prices. One source of price information is the MSH *International Drug Price Indicator Guide.* The last regular procurement price refers to the CIF price paid during the last regular MOH procurement.

Data Collection:

Where to Go	Whom to Ask	What to Get
MOH-Procurement Unit	Officer in charge of pharmaceutical purchases	List of most recent prices paid for a set of DMM antimalarial drugs Tender documents, supplier invoices
Central Medical Store	Manager or Reception Officer	
Regional government administration or Medical Store	Manager	
Health facilities	Pharmacist or Procurement Officer	Supplier invoices

This indicator is based on the list, developed by study organizers, of DMM antimalarial drugs used to treat malaria (see the Chapter 2 section, Preparing the List of DMM Antimalarial Drugs). Information on CIF prices paid by the MOH for the antimalarial drugs should apply to the last regular procurement. Any more recent ad hoc or emergency procurements that may have taken place should be compared separately to international prices. The median international prices for the antimalarial drugs may be determined by reference to the international unit prices in the MSH *International Drug Price Indicator Guide*. Do *not* use the average cost listed in the *Guide*. Instead, use the median price for each antimalarial drug.

[13]CIF, which stands for cost, insurance, and freight, is an International Commercial Term (INCOTERM) that includes the cost of the goods purchased plus the shipping and insurance costs of getting them to the designated port of entry of the destination country.

The prices in the *International Drug Price Indicator Guide* are free on board (FOB) and should be adjusted upward by 20 percent to reflect average shipping and insurance costs, that is, CIF. Specify the source of international prices and the year of both data sets. If all purchases are not done by one central agency, compile information separately by type of institution, and compute the percentage of international price for each type of purchasing institution (e.g., Regional Medical Stores, hospitals, health centers, etc.). Note the date of the most recent regular drug procurement. When making calculations, it may be necessary to convert prices paid in local currencies into U.S. dollars. **It is important to use the exchange rates in effect at the time when payments were made, and to use the edition of the *International Drug Price Indicator Guide* that corresponds with the year in which purchases were made.** If a **fixed exchange rate** was negotiated for the tender period then the fixed rate should be used.

See DAS-4: International Price Comparison Form in the *Data Collector's Guide*.

Computation & Example: The indicator should be presented as the percentages of median international prices for the set of DMM antimalarial drugs. If data are collected from different levels of the system, a separate average should be calculated for each level. The computation involves the following steps:

- Obtain CIF price for particular pack size and divide by the number of comparison units per pack. This will give the Comparison Unit Price.
- Convert price to U.S. dollars using exchange rate at time of purchase.
- Obtain FOB **median** international price for each drug from *Price Indicator Guide* for year of purchase and add 20 percent to convert to CIF price.
- The percentages are calculated for each of the DMM antimalarial drugs by dividing the purchase cost of the *comparison unit* (e.g., tablet, milliliter, etc.) at the last regular MOH procurement by the median international price of that unit and multiplying the result by 100.

$$\text{\% of Median International Price} = \frac{\text{Comparison Unit Price}}{\text{Median International Unit Price}} \times 100$$

- The average percentage for all DMM antimalarial drugs is calculated by summing their percentages and dividing by the total number on the list.

Average % of All DMM Antimalarial Drugs = Sum of Percentages of All DMM Antimalarial Drugs / Total Number of DMM Antimalarial Drugs

For purposes of illustrating the computation of the result at the CMS, assume an indicator list of three products:

Product	Comparison Unit Price	Adjusted Median International Unit Price[1]
Chloroquine 150mg tablet	0.008/tab.	0.009/tab.
Quinine 300mg tablet	0.034/tab.	0.041/tab.
Fansidar 500mg/25mg tablet	0.037/tab.	0.033/tab.

[1]The figures in this column have been adjusted to reflect estimated CIF prices.

1. The first step is to calculate the percentage for each product.

For chloroquine, the first product on the list, this is done as follows:

$$\text{\% of Median International Price} = \frac{0.008}{0.009} \times 100 = 89\%$$

Using the data in the table, the percentages for quinine and Fansidar are calculated as 83% and 112%, respectively.

2. Next, the average percentage for all three products is calculated as follows:

$$\text{Average \% of All DMM Antimalarial Drugs} = \frac{89 + 83 + 112}{3} = 95\%$$

Presentation: In country C, comparisons of drug purchase prices with median international prices were made at both the Central Medical Store and at a sample of one national and three regional hospitals. In 1992 the CMS paid an average of 95 percent of the median international price, while the hospitals paid 206 percent for the set of antimalarial drugs.

2. Average percentage of a set of unexpired DMM antimalarial drugs available in (a) MOH storage and health facilities and (b) retail drug outlets (C/R/F)

Rationale: The successful implementation of a strategy to combat malaria is dependent on the drugs being available in either the public or private sectors. If they are not, patients may not receive proper treatment. This indicator is a measure of the efficiency of the procurement and distribution system.

Definition: A drug is defined as available if even one unit of unexpired product is in stock. Since expired drugs are inappropriate for use in almost all situations, they are not counted as stock available for use.

Data Collection:

Where to Go	Whom to Ask	What to Get
Central Medical Store	Inventory Officer/Storekeeper	Inventory records and stock availability for DMM antimalarial drugs
Regional Medical Store	Manager/Storekeeper	
20 MOH health facilities	Dispenser/Pharmacist/Storekeeper	
20 Drug Retail Outlets	Dispenser/Pharmacist	Stock availability for DMM antimalarial drugs

This indicator is based on the list, developed by study organizers, of DMM antimalarial drugs used to treat malaria (see the Chapter 2 section, Preparing the List of DMM Antimalarial Drugs). First, in consultation with staff at the Central Medical Stores (CMS), Regional Medical Stores (RMS), and local health facilities, determine which of these products are normally stocked at each level. The figure for drugs *normally stocked* becomes the denominator in calculations.

Once the range of products normally held at each level has been established, the next step is to determine whether each of these normally stocked drugs is available. If any of each of the DMM antimalarial drugs is unexpired and available, record that item as "present" even if it is likely to be out of stock very soon. If all stock for a product on the list is expired, record 0. Do not worry about stock levels for this indicator.

It should also be noted that products that have different presentations, but which are otherwise the same, should be treated as a single product. For example, chloroquine injection may come in 30ml and 5ml vials. If the 5ml is in stock while the 30ml is out of stock then it should be considered available for the purposes of this indicator. Only if both presentations are out of stock would it be recorded as unavailable.

It should further be remembered that not all health facilities will normally stock the full list of antimalarial drugs and supplies. Peripheral facilities will use fewer than district and regional hospitals, for example. Bearing this in mind, DAS-2 will have to be adapted to reflect the situation at each level of health facility. For example, the full list of antimalarial drugs and supplies is seven. A dispensary/health post holding four of these items would be surveyed using form DAS-2A, for example. For a health center holding six items, DAS-2B would be used and so on. If two levels hold the same number of antimalarial drugs (a health center and a district hospital, for example), they should use the same form. This further means that the denominator for each level will be different, e.g., dispensary 4, health center 6, and so on. Further details are given in the notes provided for completing the data collection forms DAS-2A through DAS-2D.

The same data should be collected for 20 drug retail outlets using form DAS-2E. As with health facilities, account should be taken of which drugs the drug retail outlets can legitimately stock, that is, drugs that are legally registered with the Drug Regulatory Authority. This fact should be established before the data collection begins.

See DAS-2A through DAS-2E: Inventory Data Form in the *Data Collector's Guide*.

Computation & Example: This indicator is recorded as a percentage, calculated by dividing the number of unexpired DMM products found in stock by the total number of products for which availability was assessed, and multiplying by 100.

$$\text{\% of DMM Antimalarial Drugs Availability} = \frac{\text{Number of Unexpired DMM Antimalarial Drugs in Stock}}{\text{Total Number of Antimalarial Drugs Normally Stocked}} \times 100$$

Present the data in separate tables for each type of facility (CMS, RMS and peripheral health facilities) visited. For the sample of health facilities, the indicator is calculated as the average of the facility-specific averages:

$$\text{Average \% of DMM Antimalarial Drug Availability} = \frac{\text{Sum of Average \% for Each Facility}}{\text{Total Number of Facilities in Sample}}$$

To calculate the average percentage of DMM antimalarial drug availability for the sample of health facilities, carry out the following steps:

1. For one health facility with 4 unexpired DMM antimalarial drugs in stock, from a list of 7 antimalarial drugs normally stocked, the calculation is—

$$\text{\% of DMM Antimalarial Drug Availability} = \frac{4}{7} \times 100 = 57\%$$

2. For a sample of 20 health facilities, for which the sum of percentages of antimalarial drugs in stock is 960%, the average percentage of antimalarial drugs in stock is calculated as—

$$\text{Average \% of DMM Antimalarial Drug Availability} = \frac{960\%}{20} = 48\%$$

To calculate the average percentage of DMM antimalarial drug availability for the sample of drug retail outlets, carry out the following steps:

1. For one drug retail outlet with 3 unexpired DMM antimalarial drugs in stock, from a list of 7 antimalarial drugs normally stocked, the calculation is—

$$\text{\% of DMM Antimalarial Drug Availability} = \frac{3}{7} \times 100 = 43\%$$

2. For a sample of 20 drug retail outlets, for which the sum of percentages of antimalarial drugs in stock is 1,060%, the average percentage of antimalarial drugs in stock is calculated as—

$$\text{Average \% of DMM Antimalarial Drug Availability} = \frac{1{,}060\%}{20} = 53\%$$

Presentation: In a survey of 20 health facilities, where between three and five DMM indicator products were confirmed to be normally stocked, an average of 48 percent of the listed products was found in stock. The range among facilities was 25 percent to 85 percent, with the lower end of the range being associated with more peripheral health facilities. The facility-specific averages are listed below:

- Central/Regional medical stores - 85%
- District/Regional hospitals - 64%
- Health centers and posts - 48%

In a survey of 20 drug retail outlets, where between three and six DMM indicator products were confirmed to be normally stocked, an average of 53 percent of the listed products was found in stock. The range among outlets was 43 percent to 86 percent.

3. Average percentage of time out of stock for a set of DMM antimalarial drugs in MOH storage and health facilities (C/R/F)

Rationale: The percentage of time out of stock for a set of DMM antimalarial drugs gives a measure of a procurement and distribution system's performance in maintaining a constant supply of drugs. The successful treatment of malaria is dependent on the drugs being available.

Definition: Time out of stock, or stock-out time, is defined as the number of days that a product was not present in a warehouse or health facility over a recent 12-month period (usually the 12 months preceding the one during which the assessment takes place). To be considered a stock-out, there must have been none of an unexpired drug in stock. If even small quantities of an unexpired drug were present, the drug should be counted as in stock.

Data Collection:

Where to Go	Whom to Ask	What to Get
Central Medical Store	Inventory Officer/Storekeeper	Drugs that are normally stocked from the list of antimalarial drugs, number of days these normally stocked drugs were out of stock during the 12 months prior to assessment or during previous year
Regional Medical Store	Manager	
20 MOH health facilities	Dispenser/Pharmacist/Storekeeper	

This indicator is based on the list, developed by study organizers, of DMM antimalarial drugs used to treat malaria (see the Chapter 2 section, Preparing the List of DMM Antimalarial Drugs). In order to determine stock-out duration, it is necessary that there be a reasonably accurate inventory recording system (computer, ledger, bin cards, etc.) in place. As in the previous indicator, the first step is to consult with staff at each facility and determine which of the products are normally stocked. It is the number of drugs *normally stocked* that will be used in calculations. As for DAS-2, this step means that the denominator for each level will be different, e.g., dispensary 4, health center 6, and so on. Further details are given in the notes provided for completing the data collection forms.

To determine average stock-out duration, identify which of the normally stocked drugs were out of stock during the last year, and then determine for how many days the product was out of stock during that time. Ideally, this should be determined for the 12 months prior to the month in which the visit occurs. The critical issue is that the same 12-month period should be used for all health facilities and warehouses visited.

As with indicator 2, it should be noted that products that have different presentations, but which are otherwise the same, should be treated as a single product. For example, chloroquine injection may come in 30ml and 5ml vials. If the 5ml is in stock while the 30ml is out of stock then it should be considered available for the purposes of this indicator. *Only if both presentations are out of stock would it be recorded as unavailable*.

See DAS-3: Stock-Out Data Form in the *Data Collector's Guide*.

Computation & Example: Enter the historical stock data into a table, recording the names of the DMM antimalarial drugs, and the number of days of stock-out in the previous year. To compute this indicator, carry out the following steps:

- First, for each DMM antimalarial drug in the table, record the number of days out of stock for each of the last 12 months. Then sum the total numbers of days out of stock over the past 12 months for all drugs.

- Second, to record this indicator, compute the *average percentage of time that all DMM antimalarial drugs were out of stock*, within the 12-month period, by adding all the stock-out days for all drugs, dividing by 365 times the number of drugs, and multiplying by 100.

$$\text{Average \% of Time That DMM Antimalarial Drugs Were Out of Stock} = \frac{\text{Total Number of Stock-Out Days for All DMM Antimalarial Drugs}}{365 \times \text{Total Number of DMM Antimalarial Drugs Normally Stocked}} \times 100$$

Present this data in tables, and report averages for each type of facility visited (CMS, RMS, and peripheral health facilities).

For purposes of illustrating the computation, assume a DMM antimalarial drug list of three products:

Product	Total Days Out of Stock
Chloroquine phosphate 150mg tablet	36
Sulphadoxine-pyrimethamine 500mg/25mg tablet	64
Quinine injection 40mg/ml	123

Assume that in a CMS, all three of these antimalarial drugs are normally stocked.

$$\text{Average \% of Time That DMM Antimalarial Drugs Were Out of Stock} = \frac{36 + 64 + 123}{365 \times 3} \times 100 = 20\%$$

Presentation: In country C, over a 12-month period, the DMM antimalarial drugs were out of stock an average of 20 percent of the time at the Central Medical Stores. In the Regional Medical Store, the antimalarial drugs were out of stock an average of 30 percent of the time. In the sample of health clinics, the DMM antimalarial drugs were out of stock an average of 40 percent of the time.

4. Average percentage of stock records that correspond with physical counts for a set of DMM antimalarial drugs in MOH storage and health facilities (C/R/F)

Rationale: The average percentage of stock records that correspond with physical counts is a measure of the quality of the stock record-keeping system. This indicator will help to reveal inventory management problems and may point to the need for further assessments to be done of problems such as wastage, pilferage, and poor record keeping, all of which contribute to poor service delivery and financial losses.

Definition: This is the average percentage of in-stock DMM antimalarial drug inventory records that correspond exactly with a physical stock count for a set of DMM antimalarial drugs.

Data Collection:

Where to Go	Whom to Ask	What to Get
Central Medical Store	Inventory Officer/Storekeeper	Most accurate records of current stock levels for each DMM antimalarial drug, issues and receipts not entered, method of recording stocks, and physical count of unexpired stock levels
Regional Medical Store	Manager	
20 MOH health facilities	Dispenser/Pharmacist/ Storekeeper	

This indicator is based on the list, developed by study organizers, of DMM antimalarial drugs used to treat malaria (see the Chapter 2 section, Preparing the List of DMM Antimalarial Drugs).

Visit the CMS, at least one regional store if they exist in this system, and a sample of 20 health facilities. At each site, carry out the following procedure:

- Ask staff to produce the most accurate records of current stock level for each of the DMM antimalarial drugs. Ask them to produce their records for any recent issues or receipts that have not been posted in their stock level records. Using recent stock receipt and issue figures, stock records should be adjusted to bring them up to date. The physical count should then be compared to the adjusted stock record figures.

- Take note of the means used to produce these estimates (computerized system, manual ledgers, bin cards). If bin cards exist, and if they were not used to produce the best estimates, obtain a second set of data based on bin cards as a point of comparison. For reporting purposes, however, use the figures prepared by the staff for the data collection team.

- Finally, carry out a physical count of the unexpired stock levels for these drugs, and record the number of units for each DMM antimalarial drug in stock. The expired units should not be counted. Antimalarial drugs that are not normally stocked by the facility should be excluded.

- All pack sizes and presentations should be included separately for this indicator.

See DAS-2A through DAS-2D: Inventory Data Form in the *Data Collector's Guide*.

Computation & Example: For the set of antimalarial drugs, calculate the percentage of records checked that correspond exactly with the physical counts according to the tally and the ledger. To do this, divide the number of records for which no discrepancy was found by the total number of records checked, and multiply this result by 100.

$$\text{\% of Stock Records Corresponding with Physical Counts} = \frac{\text{Number of Stock Records with No Discrepancies}}{\text{Total Number of Records Examined}} \times 100$$

Present the data in separate tables for each type of facility in the sample (CMS, RMS, or peripheral health facilities). For the sample of health facilities, the indicator is calculated as the average of the facility-specific averages:

$$\text{Average \% of Stock Records Corresponding with Physical Counts} = \frac{\text{Sum of Average \% for Each Facility}}{\text{Total Number of Facilities in Sample}}$$

For purposes of illustrating this computation, assume a DMM antimalarial drug list of three products:

Product	Record	Count
Chloroquine 150mg tablet	10,000	10,000
Quinine 300mg tablet	1,000	990
Fansidar 500mg/25mg	88	87

To calculate the percentage of stock records that correspond exactly with physical counts, carry out the following steps:

For one health facility, using the DMM antimalarial drug list above—

1. The number of records examined = 3

2. The number of records with no discrepancy = 1

$$\text{\% of Stock Records Corresponding with Physical Stock Counts} = \frac{1}{3} \times 100 = 33\%$$

For a sample of 20 health facilities, for which the sum of percentages of stock records that correspond exactly with physical counts is 600 percent, the average percentage of DMM antimalarial drugs that correspond exactly with physical counts is calculated as—

$$\text{Average \% of Stock Records Corresponding with Physical Counts} = \frac{600\%}{20} = 30\%$$

Presentation: After adjusting for issue tickets not yet entered in the records at the Central Medical Store in country Q, the percentage of records for three DMM antimalarial drugs that corresponded exactly with physical counts was 33 percent. The average percentage of health facility records that corresponded exactly with physical counts was 30 percent, with the range among facilities from 10 percent to 60 percent.

Drug Use Study Indicators

These indicators (5 through 13) focus on drug use practices for treating malaria as currently taking place in the health system. Most developing countries have adopted policies and treatment guidelines for malaria. However, despite years of promotion, health care providers frequently do not follow these guidelines when prescribing drugs. Whatever the intervention attempted in response to this problem, there are four needs that are constant: identifying the specific prescribing behaviors to change, intervening to bring about positive change, assessing the extent to which change takes place, and periodic monitoring of the status of problem behaviors.

Data collection for this study will involve a retrospective review of patient records in health facilities using standard data collection forms, copies of which are provided in the *Data Collector's Guide*. Retrospective data collection requires that adequate sources of data exist (i.e., records that offer a method of selecting a random sample of patient encounters that took place within a defined period of time and the specific names and routes of administration of all drugs prescribed).

To assess certain aspects of the interaction between health workers and caregivers, direct observation will be used. This observation will be followed by exit poll interviews of the caregivers to allow a comparison of what was told to the caregiver by the health worker and what information concerning drug treatment was actually understood or retained by the caregiver.

For the simulated purchases method, data collectors posing as customers seeking help for treating malaria will visit retail drug outlets. For the simulated patients method, data collectors posing as patients or caregivers seeking help for treating malaria will visit government health facilities. In both scenarios, the data collector will present himself or herself (without a prescription) as the caregiver of a child who has had, for example, a fever for two days. The data collector will ask the drug seller for advice about what products are best to treat this condition or the health worker for advice on treatment. All information is recorded on information sheets by the data collector after leaving the store.

By using the indicators, the user will be able to develop a profile of current practices for treating malaria. The information gathered can be used as a basis for (1) identifying factors that influence particular behaviors and (2) designing interventions for bringing about improvements.

5. Percentage of MOH health facilities visited that had a copy of official standard treatment guidelines for malaria (F)

Rationale: This indicator is used to measure the level of access to information to promote effective care and management of malaria based on treatment guidelines adopted by the MOH of the country involved.

Definition: To qualify as an official manual or standard treatment guidelines (STGs) for the purposes of this indicator, a document must be intended as a clinical reference for health care providers who see and sometimes treat malaria patients, and it must present information on the treatment of malaria in that particular country, including the examination, care and drug therapy, and follow-up of the patient. This indicator measures the presence of the current edition of an official manual or STGs.

Data Collection:

Where to Go	Whom to Ask	What to Get
MOH	Malaria Program Manager	Most recent copy of manual or STGs
20 MOH health facilities	Health Officer/Director/ Manager Facility Manager	Most recent copy of manual or STGs

Such a manual or STGs must officially exist for this indicator to be meaningful. If so, obtain the most recent copy of the manual or STGs that has been prepared to provide impartial information about how to care for malaria sufferers. Evaluate whether the information in the manual or STGs meets all the following criteria, specified in the definition above:

- The document is intended as a clinical reference for health care providers.
- The document presents information on the examination, treatment (including drug therapy), and follow-up care for malaria.

Data for this indicator are collected by survey of a sample of 20 health facilities. At each site, staff are asked to produce a copy of a document that meets the above criteria.

See DUS-1: Medical Records Review Form in the *Data Collector's Guide*.

Computation & Example: This indicator is a percentage. It is computed as the number of facilities at which an official manual or **STGs** is found, divided by the total number of facilities in the sample and multiplying by 100, to convert the decimal to a percentage.

$$\text{\% Facilities with Official Manual or STGs} = \frac{\text{Number of Facilities with Official Manual or STGs}}{\text{Number of Facilities in Sample}} \times 100$$

$$\text{\% Facilities with Official Manual or STGs} = \frac{9}{20} \times 100 = 45\%$$

Presentation: In country Y, a national manual exists: it was adapted in 1996. The manual is intended for use by physicians, nurses, and other health care personnel who treat malaria. It contains information on examination, care (including drug therapy), and follow-up services for malaria sufferers. An indicator study carried out in country Y revealed that in 45 percent of health facilities, or nine health facilities out of a sample of 20 surveyed, staff could produce a copy of the 1996 edition of the manual.

6. Percentage of encounters with patients diagnosed with uncomplicated malaria who are prescribed an antimalarial consistent with treatment guidelines

Rationale: This indicator measures the degree of adherence to Standard Treatment Guidelines for malaria. Following STGs for treating uncomplicated malaria is important in order to treat the patient in a timely and effective manner, contain treatment costs, and reduce the risk of contributing to the development of drug resistance.

Definition: This indicator measures the degree of adherence with national guidelines for treating uncomplicated malaria. There are no internationally agreed standards for the diagnosis of malaria. Patients may complain of fever that is often periodic and accompanied by headache, chills, nausea, vomiting, and joint and muscle aches. In general, the simple existence of a fever, even in high-risk areas, may not be enough to indicate malaria as a fever is present in many people sick enough to go to a clinic. Nevertheless, because uncomplicated malaria can rapidly progress to the severe disease, any diagnostic approach must have a high sensitivity in order to ensure that as many malaria patients as possible receive antimalaria treatment. The Integrated Management of Childhood Illness (IMCI) approach for children in endemic areas, for example, achieves this by the use of fever or a recent history of fever as the diagnostic criterion.

Although this certainly leads to substantial overtreatment of nonmalaria patients with malaria drugs, many countries judge it an acceptable price to pay as long as the drugs prescribed are cheap, safe, and effective. This is especially the case in areas with limited access to laboratory testing facilities. Based upon this line of argument, and unless national guidelines for a particular country indicate otherwise, the existence of fever in endemic areas is adopted as the basis for this indicator.

An appropriate antimalarial includes those antimalarials listed in the national treatment guidelines of a particular country. International norms include, for example, chloroquine and the combination sulfadoxine and pyrimethamine (Fansidar) as appropriate oral antimalarials for the treatment of uncomplicated malaria. An antimalarial that is not retained by the country as the choice treatment for malaria will be considered inappropriate.

Data Collection:

Where to Go	Whom to Ask	What to Get
20 MOH health facilities	Medical Records Officer/ Health Facility Manager/ Pharmacist	Identify a sample of 30 malaria encounters per health facility and determine the number who were prescribed antimalarials. Identify encounters by consulting daily registers, patient records, prescription slips. Should records be unavailable or incomplete, then the data should be collected either through simulated patient encounters or observation. In the case of a **Simulated Patient Encounter** the number of malaria encounters who were prescribed antimalarials will be determined by the number of simulated patient exercises conducted. The sample size for this is 20 sites, so 20 simulated patient exercises will be conducted. The sample size for **observation** should also be 20.
20 Drug retail outlets	Data collected through simulated purchase	The sample size for drug retail outlets is 20 sites, so 20 simulated purchases will be conducted.

Before the study, organizers should decide which antimalarial is the appropriate one for the area where the survey takes place. Organizers should also discuss and reach consensus on a list of local terms used to describe symptoms that may be listed in health facility records to denote cases of malaria. Likewise, a list should be drawn up of all terms that cover conditions that correspond with the no-malaria fever. Efforts should be made first to gather the data retrospectively from medical records. If the data are not available from records, then as an alternative, the data can be collected prospectively through either a simulated patient encounter or by observation. Data should be presented using analysis of data collected with a single data collection method.

In many areas malaria is seasonal, which may limit the usefulness of the prospective data collection if the survey falls outside the malaria season. (See description of sampling methods in the Chapter 2 section, Selecting Data Collection Sites.)

Use the list of terms described above to select a sample of 30 patient encounters diagnosed as malaria from each MOH health facility. All drugs prescribed should be transcribed on the data collection forms. Count the number of encounters in which an antimalarial was prescribed.

Note: Malaria encounters may be difficult to identify at the health facility level in areas with low malaria risk or in areas with a clear seasonal pattern for malaria. In these areas, review four months of records, starting from the last month of the malaria season. If fewer than five cases in total have been identified, abandon the process for malaria in that facility. If five or more cases have been identified, continue the selection process for the 12- month period and stop, even if fewer than 30 encounters have been identified. The time required to review 12 months of records for a probable data set of less than 15 cases is not efficient use of the limited time available.

For drug retail outlets, follow the simulated purchases scenario for malaria outlined in the *Data Collector's Guide*.

See DUS-1A and DUS-1B: Medical Records Review Form; DUS-2: Observation of Health Worker Data Form; DUS-3: Exit Poll Interview Form; DUS-4: Simulated Purchase Data Form; and DUS-5: Simulated Patient Data Form in the *Data Collector's Guide*.

Computation & Example: For each facility in a sample, the indicator is recorded as a percentage of the total number of patient encounters **surveyed**. The percentage is computed by dividing the number of malaria patient encounters during which an antimalarial is prescribed for malaria by the total number of malaria patient encounters surveyed, and multiplying by 100. The overall indicator is the average of the facility- specific percentages. Along with this average, provide range figures.

$$\text{\% of Malaria Encounters Prescribed an Appropriate Antimalarial} = \frac{\text{Prescribed Antimalarials Consistent with STGs}}{\text{Total Number of Malaria Encounters Surveyed}} \times 100$$

- For example, results from one health facility are calculated as follows:

$$\text{\% of Malaria Encounters Prescribed an Appropriate Antimalarial} = \frac{8}{24} \times 100 = 33\%$$

- If for 20 health facilities surveyed, data for a sample of 518 patient encounters showed that a total of 406 patient encounters received an appropriate antimalarial for the treatment of uncomplicated malaria, then the average for all facilities would be—

$$\text{\% of Malaria Encounters Prescribed an Appropriate Antimalarial for All Facilities} = \frac{406}{518} \times 100 = 78\%$$

- If a sample of 20 drug retail outlets where malaria simulated purchases were conducted showed that a total of 14 patient encounters received appropriate antimalarials for the treatment of uncomplicated malaria, then the average for the 20 drug retail outlets would be—

$$\text{\% of Malaria Encounters Prescribed an Appropriate Antimalarial} = \frac{\text{Total Number of Malaria Encounters Prescribed Antimalarials}}{\text{Total Number of Simulated Purchases}} \times 100$$

$$\text{\% of Malaria Encounters Prescribed an Appropriate Antimalarial} = \frac{14}{20} \times 100 = 70\%$$

- If a sample of 20 health facilities where simulated patient exercises were conducted showed that a total of 17 patient encounters received appropriate antimalarials for the treatment of uncomplicated malaria, then the average for the 20 drug retail outlets would be—

$$\text{\% of Malaria Encounters Prescribed an Appropriate Antimalarial} = \frac{\text{Total Number of Malaria Encounters Prescribed Antimalarials}}{\text{Total Number of Simulated Patients}} \times 100$$

$$\text{\% of Malaria Encounters Prescribed an Appropriate Antimalarial} = \frac{17}{20} \times 100 = 85\%$$

Presentation: In a survey of 20 health facilities in country Z, an appropriate antimalarial was prescribed for the treatment of malaria during 78 percent of all outpatient encounters classified as having uncomplicated malaria, with a range of 38 percent to 89 percent among facilities.

In a survey conducted through simulated purchases of 20 drug retail outlets in the same country Z, an appropriate antimalarial was prescribed in 14 encounters presenting with complaints compatible with uncomplicated malaria, or 70 percent of those surveyed.

In a survey conducted through simulated patient encounters of 20 health facilities in the same country Z, an appropriate antimalarial was prescribed in 17 encounters presenting with complaints compatible with uncomplicated malaria, or 85 percent of those surveyed.

7. Percentage of encounters with patients diagnosed with uncomplicated malaria that are prescribed quantities of antimalarials consistent with treatment guidelines and sufficient to complete a full course of treatment (F/D)

Rationale: Resistance to chloroquine is a central problem in treating malaria. Moreover, there is increasing evidence that resistance to second-line drugs such as sulphadoxine- pyrimethamine (SP/Fansidar) is also growing in some parts of the world. A key element of any strategy to slow the spread of resistance is that patients complete the full course of drug therapy prescribed for them.

However, before patients can complete a full course of treatment, the health worker must not only prescribe the right drugs, but prescribe them in the right quantities. This indicator measures the extent to which malaria patients/caregivers are prescribed sufficient drugs by the public health facility or retail drug outlet to complete a full course of treatment.

Definition: A full course of treatment is defined on the basis of the standard treatment guidelines for a given **country**. Normally, for example, a three-day course of treatment with chloroquine for a 90kg adult with uncomplicated malaria would be—

- On days 1 and 2, take 10mg per kg orally, i.e., six tablets of 150mg tablets on day 1, and six tablets on day 2
- On day 3, take 5mg per kg orally, i.e., three tablets of 150mg each.
- The total number of tablets required for the course of treatment is 15 chloroquine tablets of 150mg each.

For SP, for example, a full course for an adult would normally be three tablets.

Data Collection:

Where to Go	Whom to Ask	What to Get
20 MOH Health Facilities	Health facility manager for permission to conduct exit poll interviews and to review health records	Identify a sample of 30 malaria encounters per health facility and determine the type and quantity of prescribed antimalarials. If possible, identify encounters retrospectively by consulting daily registers, patient records, and prescription slips. Should records be unavailable or incomplete, then the data should be collected through simulated patient encounters. If exit polls are the data collection method used, gather data for 10 to 15 of the encounters at each health facility by conducting exit poll interviews. Use the same interviews used for indicator 8. In the case of a **Simulated Patient Encounter,** the sample size is 20 sites, so 20 simulated patient exercises will be conducted. Compare quantities of each drug prescribed against the recommendations made in the standard treatment guidelines.
20 Retail Drug Outlets	Data collected through simulated purchase. Store managers should be unaware of the process so no permission is needed.	Use **Simulated Purchase Encounter** to collect prescribing data. Compare quantities of each drug prescribed against the recommendations made in the standard treatment guidelines.

See DUS-1A: Medical Records Review Form; DUS-3: Exit Poll Interview Form; DUS-4: Simulated Purchase Data Form; and DUS-5: Simulated Patient Data Form in the *Data Collector's Guide.*

Computation & Example: For each MOH facility and drug retail outlet in the sample, indicators are recorded as percentages, computed by dividing the number of malaria prescriptions with quantities sufficient to complete a course of treatment by the total number of malaria prescriptions and multiplying this by 100. The overall indicator is an average of these facility-specific percentages. Along with this average, provide the range of figures.

MOH Facility

$$\text{\% of Prescriptions Providing for a Full Course of Treatment} = \frac{\text{Number of Malaria Prescriptions Sufficient for a Full Course}}{\text{Number of Malaria Prescriptions}} \times 100$$

- The result for one MOH health facility is calculated as follows:

$$\text{\% of Prescriptions Providing for a Full Course of Treatment} = \frac{4}{13} \times 100 = 31\%$$

- If, for 20 MOH health facilities, data for a sample of 194 exit poll interview/retrospective encounters showed that 86 prescriptions were sufficient for a full course, of 155 prescriptions given to patients/caregivers, then the average for all MOH facilities would be calculated as follows:

$$\text{Average \% of Prescriptions Providing for a Full Course of Treatment} = \frac{86}{155} \times 100 = 55\%$$

Drug Retail Outlet

$$\text{\% of Prescriptions/Recommendations Providing for a Full Course of Treatment} = \frac{\text{Number of Malaria Prescriptions/Recommendations Sufficient for a Full Course}}{\text{Number of Malaria Prescriptions/Recommendations}} \times 100$$

- If, for 20 drug retail outlets, data for a sample of 20 simulated patient encounters showed that seven prescriptions/recommendations were sufficient for a full course, then the average for all MOH facilities would be calculated as follows:

  $$\text{\% of Prescriptions Providing for a Full Course of Treatment} = \frac{7}{20} \times 100 = 35\%$$

Presentation: In country P, for a sample of 20 health facilities, an average of 55 percent of malaria prescriptions presented were for quantities sufficient for a full course of treatment, with a range from 31 percent to 63 percent among health facilities. For 20 drug retail outlets, an average of 35 percent of malaria prescriptions and/or recommendations were for quantities sufficient for a full course of treatment.

8. Percentage of prescribed antimalarial drugs actually dispensed by public health facilities (F/D)

Rationale: This indicator measures the ability of a sample of health facilities to dispense the prescribed antimalarial drugs to malaria patients or caregivers of malaria patients.

Definition: Drugs that are actually dispensed are defined as prescribed antimalarial drugs that are dispensed from the health facility. This indicator is based only on the prescriptions presented for dispensing at public health facilities in malaria encounters.

Data Collection:

Where to Go	Whom to Ask	What to Get
20 MOH health facilities	Health facility supervisor for permission to conduct exit poll interviews	Using patient and/or dispensing records, identify the number of drugs dispensed and the total number of drugs that were prescribed in a sample of 30 malaria dispensing encounters at each health facility. Should records be unavailable or incomplete, collect the same information from a sample of 10 to 15 malaria dispensing encounters at each health facility by conducting exit poll interviews.

Note on Exit Polls: At each of the 20 MOH health facilities, data collectors conducting the exit poll interviews should use the same sample of malaria encounters used for indicator 7. Conduct the exit poll interviews as described in the *Data Collector's Guide*. Include only malaria patients or caregivers of malaria patients needing curative care.

See DUS-1: Medical Records and Facility Resources Review Form; DUS-3: Exit Poll Interview Form in the *Data Collector's Guide.*

Computation & Example: For each MOH facility in the sample, indicators are recorded as percentages, computed by dividing the number of drugs actually dispensed by the total number of prescribed drugs that were presented for dispensing, and multiplying this quotient by 100. The overall indicator is an average of these drug outlet–specific percentages. Along with this average, provide the range figures.

$$\text{\% of Prescribed Drugs That Are Dispensed} = \frac{\text{Number of Drugs Actually Dispensed}}{\text{Number of Prescribed Drugs Presented for Dispensing}} \times 100$$

- The result for one MOH health facility is calculated as follows:

$$\text{\% of Prescribed Drugs That Are Dispensed} = \frac{7}{13} \times 100 = 54\%$$

- If, for 20 MOH health facilities, data for a sample of 194 exit poll interview encounters showed that 115 prescribed drugs were actually dispensed, of 155 prescriptions presented for dispensing, then the average for all MOH facilities would be calculated as follows:

$$\text{Average \% of Prescribed Drugs That Are Dispensed for All MOH Facilities} = \frac{115}{155} \times 100 = 74\%$$

Presentation: In country P, for a sample of 20 MOH health facilities, an average of 74 percent of prescribed drugs presented for dispensing were actually dispensed, with a range from 47 percent to 90 percent among health facilities.

9. Percentage of cases where the quantity of antimalarial drugs dispensed by public health facilities was sufficient to complete a course of treatment

Rationale: Resistance to chloroquine is a central problem in treating malaria. Moreover, there is increasing evidence that resistance to second-line drugs such as sulphadoxine-pyrimethamine (Fansidar) is also growing in some parts of the world. A key element of any strategy to slow the spread of resistance is that patients complete the full course of drug therapy prescribed for them.

In many parts of the world, problems of availability or cost mean that patients do not always leave a clinic with sufficient tablets and so on for a full course of treatment. There is a great deal of evidence to suggest that, in these circumstances, patients do not complete their course of treatment. In order to encourage patients to take a full course it is, therefore, very helpful if they can receive enough doses to complete a full course of treatment. This indicator measures the extent to which malaria patients/caregivers are dispensed sufficient drugs by the public health facility to complete a full course of treatment.

Definition: A full course of treatment is defined on the basis of the standard treatment guidelines for a given country. For example, a three-day course of treatment with chloroquine for a 90kg adult with uncomplicated malaria would be—

- On days 1 and 2, take 10mg per kg orally, i.e., six tablets of 150mg each on day 1, and six tablets on day 2.
- On day 3, take 5mg per kg orally, i.e., three tablets of 150mg tablets each.
- The total number of tablets required for the course of treatment is 15 chloroquine tablets of 150mg each.

Data Collection:

Where to Go	Whom to Ask	What to Get
20 MOH Health Facilities	Health facility manager for permission to conduct exit poll interviews	Using patient and/or dispensing records, record the quantities of each drug dispensed that were prescribed in a sample of 30 malaria dispensing encounters at each health facility. Compare quantities of each drug against the recommendations made in the standard treatment guidelines. Should records be unavailable or incomplete, collect the same information from a sample of 10 to 15 malaria dispensing encounters at each health facility by conducting exit poll interviews.

Note on Exit Polls: At each of the 20 MOH health facilities, data collectors conducting the exit poll interviews should use the same sample of malaria encounters used for indicators 7 and 8. Conduct the exit poll interviews as described in the *Data Collector's Guide.* Include only malaria patients or caregivers of malaria patients needing curative care.

See DUS-1: Medical Records and Facility Resources Review Form; DUS-3: Exit Poll Interview Form in the *Data Collector's Guide.*

Computation & Example: For each MOH facility in the sample, indicators are recorded as percentages, computed by dividing the number of malaria prescriptions dispensed in quantities sufficient to complete a course of treatment by the total number of malaria prescriptions and multiplying this by 100. The overall indicator is an average of these facility-specific percentages. Along with this average, provide the range of figures.

$$\text{\% of Prescribed Drugs Dispensed for a Full Course of Treatment} = \frac{\text{Number of Malaria Prescriptions Fully Dispensed}}{\text{Number of Malaria Prescriptions Dispensed}} \times 100$$

- The result for one MOH health facility is calculated as follows:

$$\text{\% of Prescribed Drugs Dispensed for a Full Course of Treatment} = \frac{4}{13} \times 100 = 31\%$$

- If, for 20 MOH health facilities, data for a sample of 194 exit poll interview/retrospective encounters showed that 86 prescriptions were actually dispensed for a full course, of 155 prescriptions presented for dispensing, then the average for all MOH facilities would be calculated as follows:

$$\text{Average \% of Prescriptions Dispensed for a Full Course of Treatment} = \frac{86}{155} \times 100 = 55\%$$

Presentation: In country P, for a sample of 20 MOH health facilities, an average of 55 percent of malaria prescriptions presented for dispensing were actually dispensed in quantities sufficient for a full course of treatment, with a range from 31 percent to 63 percent among health facilities.

10. Average cost of drugs prescribed as a percentage of costs if Standard Treatment Guideline norms for treatment were followed (F/D)

Rationale: One of the basic tenets of rational drug management is that the use of standardized treatment guidelines, if followed, will provide cost-effective, appropriate care that is likely to be cheaper than the cost of care if guidelines are not followed. On the assumption that following STG results in the optimal cost, this indicator is useful for monitoring and controlling drug treatment costs.

Definition: This indicator measures the average cost of drugs prescribed currently for different age groups with malaria in the public and private sectors and compares the average to what drug treatment would cost if standard treatment guidelines were followed for those age groups. The comparison is depicted mathematically as a percentage for each age group in each sector.

Data Collection:

Where to Go	Whom to Ask	What to Get
20 MOH health facilities	Medical Records Officer/ Health Facility Manager/ Pharmacist	Determine all drugs prescribed for a malaria encounter for a sample of 30 patients per patient group per facility by consulting daily registers, patient records, prescription slips. Should records be unavailable or incomplete then collect the same information by either observing patient encounters or by conducting **simulated patient** encounters. Use the same sample of malaria encounters identified for indicators 6, 7, and 9.
20 Drug retail outlets	Data collected through simulated purchase. Store managers should be unaware of the process so no permission is needed.	Determine all drugs prescribed for a malaria encounter for a sample of 20 simulated purchases for malaria.

Before collecting the sample of encounters, organizers should meet with the data collectors to discuss the proper way to collect the data. All drugs per malaria encounter should be recorded. (To avoid confusion or the need for interpretation by data collectors, all drugs prescribed should be transcribed exactly as listed in the patient record to the data collection forms. In addition to the name of the drug, it is important to record the dosage strength, dosage form, and length of drug therapy or amount of drug dispensed. Verifying cost information can be carried out during data analysis).

Include only outpatients seeking curative care for malaria. Efforts should be made first to gather the data retrospectively from daily registers, medical records, or prescription slips. If the data are not available from records, then as an alternative, the data can be collected prospectively from observation, exit poll interviews, and simulated patient encounters. (See description of sampling methods in the Chapter 2 section, Selecting Data Collection Sites.)

Careful note should be made of the different STGs and hence different costs associated with different age groups. For example, treatment for a child will be different from treatment for an adult; the STG costs will therefore be different. Each age group should be reported on separately. For drug retail outlets, the recommended scenario for the simulated purchase is only for a 12-year-old child. The denominator is therefore only for the STG cost for this age group.

See DUS-1: Medical Records Review Form; DUS-2: Observation of Health Worker Data Form; DUS-4: Simulated Purchase Data Form; and DUS-5: Simulated Patient Data Form in the *Data Collector's Guide*.

Computation & Example: This indicator is recorded as a percentage for each age group for which data are collected and that has a different treatment guideline. First, for example, for a sample of adult encounters, calculate the total cost of all drugs prescribed for a malaria encounter. This should be divided by the total cost of the drug treatment recommended in malaria treatment guidelines for adults. (To determine the STG cost, all costs should be based on the prices collected in the drug retail outlets on data collection form DUS-1. Ideally, the median price of all of the prices collected for a drug should be used for the calculations, which are based on the country's standard treatment for a disease.) Then, multiply the result by 100.

Adults

$$\text{Percentage of Costs If National Norms of Treatment Were Followed} = \frac{\text{Total Cost of Drugs Prescribed for Adults with Malaria}}{\text{Total Cost of Malaria Drugs Recommended by STGs}} \times 100$$

- For example, results from one health facility are as follows:

$$\text{Percentage of Costs If National Norms of Treatment Were Followed} = \frac{\$5.05}{\$2.07} \times 100 = 244\%$$

- Another example where results for adults from one health facility for treatment were less than STG costs is as follows:

$$\text{Percentage of Costs If National Norms of Treatment Were Followed} = \frac{\$1.77}{\$2.07} \times 100 = 86\%$$

- If for 20 health facilities surveyed, data for a sample of 400 adult malaria patient encounters showed a total cost of $1,412 for drug treatment, then the average for all facilities would be—

$$\text{Average Cost of Drugs Prescribed for Malaria Treatment in All Facilities} = \frac{\$1,412}{400} = \$3.53$$

$$\text{Percentage of Costs If National Norms of Treatment Were Followed} = \frac{\$3.53}{\$2.07} \times 100 = 170\%$$

Children between 1 and 5

$$\text{Percentage of Costs If National Norms of Treatment Were Followed} = \frac{\text{Total Cost of Drugs Prescribed For Children with Malaria}}{\text{Total Cost of Malaria Drugs Recommended by STGs}} \times 100$$

- For example, results from one health facility for children are as follows:

$$\text{Percentage of Costs If National Norms of Treatment Were Followed} = \frac{\$4.35}{\$1.57} \times 100 = 277\%$$

- Another example where results for children from one health facility for treatment were less than STG costs is as follows:

Percentage of Costs If National Norms of Treatment Were Followed	=	$1.14 / $1.57	x	100	=	73%

- If for 20 health facilities surveyed, data for a sample of 200 childhood malaria encounters showed a total cost of $657 for drug treatment, then the average for all facilities would be—

Average Cost of Drugs Prescribed for Malaria Treatment in All Facilities	=	$657 / 200	=	$3.29		
Percentage of Costs If National Norms of Treatment Were Followed	=	$3.29 / $1.57	x	100	=	210%

- If a survey of 20 drug retail outlets conducted through 20 simulated purchases for malaria showed a total cost of $162 for drug treatment, then the average for the 20 drug retail outlets would be—

Average Cost of Drugs Prescribed for Malaria Treatment in Drug Retail Outlets	=	$162 / 20	=	$8.10		
Percentage of Costs If National Norms of Treatment Were Followed	=	$8.10 / $2.07	x	100	=	391%

Presentation: In a survey of 20 health facilities in country T, the average cost of drugs prescribed for the treatment of adult malaria was $3.53. This cost was almost double, or 170 percent, the cost of drug treatment recommended by the Standard Treatment Guidelines. For children between one and five treated at the same group of health facilities, the average cost of drugs was $3.29. This amount was more than double the cost, 210 percent, of treatment recommended by the STG. For 20 drug retail outlets in the same country, the cost for 12-year-old children was 391 percent higher.

11. Percentage of malaria patients and/or caregivers of malaria patients who could correctly describe how to give the prescribed antimalarial medication (F)

Rationale: This indicator is useful to measure the potential for nonadherence and possible treatment failure because of the lack of knowledge of patients and caregivers on how to administer medication correctly.

Definition: Ideally, every patient and caregiver should know the name of the drug, what the drug is prescribed for, the dose, the frequency, how to administer the drug, and the number of days the drug should be given. However, there are a few key items that are more critical than others. To correctly describe how to take the medication, the patient/caregiver should know the dose to administer, how many times a day, for how many days, and how to administer. All four of these items should be mentioned verbally by the patient/caregiver for the encounter to be considered correct.

Data Collection:

Where to Go	Whom to Ask	What to Get
20 MOH health facilities	Health facility for permission to conduct exit poll interviews with malaria patients/caregivers of malaria patients	Using exit poll interviews ask 10 to 15 patients/caregivers needing curative care for malaria in each health facility to describe how they are going to take/give the drugs prescribed. If exit poll interviews were used for indicators 7, 8, and 9, then the same interviews should be used for this indicator.

At each of the 20 MOH health facilities, data collectors should conduct exit poll interviews with a sample of 10 to 15 patients. Where applicable, use the same sample of patient/caregiver encounters used for previously described indicators 7, 8, and 9. Conduct the exit poll interviews as described in the *Data Collector's Guide*. Include only patients/caregivers of patients needing curative care for uncomplicated malaria.

See DUS-3: Exit Poll Interview Form in the *Data Collector's Guide*.

Computation & Example: For each MOH facility in the sample, indicators are recorded as percentages, computed by dividing the number of patients/caregivers, and multiplying this quotient by 100. The overall indicator is an average of these drug outlet–specific percentages. Along with this average, provide the range figures.

$$\text{Number of Patients Who Correctly Describe How to Give the Medication} = \frac{\text{Number of Patients/Caregivers Who Correctly Describe How to Give Medication}}{\text{Number of Patients/Caregivers Interviewed}} \times 100$$

- The result for one MOH health facility is calculated as follows:

$$\text{\% of Patients Who Correctly Describe How to Give the Medication} = \frac{7}{13} \times 100 = 54\%$$

- If, for 20 MOH health facilities, data for a sample of 194 exit poll interview encounters showed that 101 patients/caregivers described correctly how to give the medication, then the average for all MOH facilities would be calculated as follows:

$$\text{Average \% of Patients Who Correctly Described How to Give the Medication} = \frac{101}{194} \times 100 = 52\%$$

Presentation: In country P, for a sample of 20 MOH health facilities, an average of 52 percent of patients/caregivers correctly described how to give the medication, with a range from 37 percent to 90 percent among health facilities.

12. Percentage of health workers and drug retail outlets that provided some information to malaria patients and/or caregivers on how to give the recommended drug(s) (F/D)

Rationale: This indicator measures whether health workers are able to communicate to patients how to take their medication. This component is important in gaining an understanding of patient use of medication and patient education.

Definition: The definition for "some information" includes the dose and the frequency of medication use, how to prepare the drug, whether to take with food, or any potential side effects or symptoms associated with the drug. If the health worker explains at least one of these aspects to the patient, then, for this indicator, it will be considered that the health worker has provided information regarding the prescribed drug. Failure to directly discuss any of these issues with the patient will be considered as not providing any information.

Data Collection:

Where to Go	Whom to Ask	What to Get
20 MOH health facilities	Data collection is done as a simulation. Health workers should be unaware of the process so no permission is needed from the health facility.	A **Simulated Patient Exercise** will be used to collect data. In this case, the number of malaria encounters prescribed antimalarials will be determined by the number of simulated patient exercises conducted. The sample size for this is 20 sites, so 20 simulated patient exercises will be conducted. **Observation** can be used should it be either impossible or undesirable to use the simulated patient technique for data collection.
20 Drug retail outlets	Data collection is done as a simulation. Store managers should be unaware of the process so no permission is needed.	Determine the prescribing practice for a sample of 20 simulated purchases for malaria.

For each simulated encounter, the data collector will note whether any information regarding the drug was given. The type of information the data collector should listen for is—

- What is the name of the drug?
- What is the dose?
- What is the frequency of the dose?
- How long should the patient take the drug?
- Are there any special instructions regarding the administration of the drug?

For example, if a patient is prescribed chloroquine then the observer should expect to hear instructions about taking the medication with food and the importance of completing the full course of treatment. If the data collector did not hear any of the above questions addressed, then he or she can consider that during the encounter, the practitioner did not provide any information.

See DUS-2: Observation of Health Worker Data Form; DUS-4: Simulated Purchase Data Form; and DUS-5: Simulated Patient Data Form in the *Data Collector's Guide*.

Computation & Example: The data collector should note whether the practitioner provides any information regarding any of the drugs for each encounter. The indicator is a percentage. Therefore, the number of practitioners providing information is divided by total number of encounters, and should be multiplied by 100 to obtain a percentage. Along with this average, provide the range figures.

$$\text{Percentage of Health Workers Who Provided Information to Patient/Caregiver on How to Take/Give the Recommended Drug(s)} = \frac{\text{Total Number of Health Workers Providing Information}}{\text{Total Number of Encounters}} \times 100$$

- If, for 20 health facilities surveyed, data for a sample of 20 patient encounters showed that in 16 encounters, health workers provided some information to the patient on how to give the recommended drug(s), then the average for all facilities would be calculated as follows:

$$\text{Percentage of Health Workers Who Provided Information to Patient/Caregiver on How to Take/Give the Recommended Drug(s)} = \frac{16}{20} \times 100 = 80\%$$

- If, for 20 drug retail outlets surveyed, data for a sample of 20 patient/caregiver encounters showed that 15 were provided with some information on how to take/give the recommended drug(s), then the average for all drug retail outlets would be calculated as follows:

$$\text{Percentage of Drug Retail Outlets That Provided Information to Patient/Caregiver on How to Take/Give the Recommended Drug(s)} = \frac{15}{20} \times 100 = 75\%$$

Presentation: In a survey of 20 health facilities in country T, an average of 80 percent of health workers provided some information to patient/caregiver on how to give the recommended drug(s).

In a survey conducted at 20 drug retail outlets in the same country T, an average of 75 percent of health workers provided some information to patient/caregiver on how to give the recommended drug(s).

Supplemental Indicator

For the purpose of this manual, a supplemental indicator is defined as one whose use depends upon it being in line with MOH policy in the country carrying out the assessment. There is one supplemental indicator in the DMM that can be used as part of the Drug Use Study. This indicator addresses the giving of presumptive antimalarial treatment as a routine part of antenatal care.

Not all countries follow this regimen; some administer to all pregnant women while others do not have a policy on it. Before including this indicator in the DMM assessment it will be necessary to clarify the country's policy with the national malaria program. **It can only be included if the particular country has a policy providing for giving presumptive antimalarial treatment to pregnant women.**

13. Percentage of encounters with pregnant women living in endemic areas who are prescribed an appropriate antimalarial prophylaxis at antenatal clinics (F)

Rationale: Historically, the choice of the best antimalarial drug for prophylactic use during pregnancy has been controversial because of the perceived or real dangers to the development of the fetus. This choice has been further complicated by drug resistance developing against many of the antimalarial drugs believed to be safe for use during pregnancy. While there are antimalarial drugs that should not be used during pregnancy, it has become apparent that risks associated with malaria during pregnancy often outweigh the risks posed by antimalarial drug use during pregnancy.[14] On the basis that infection with *falciparum* malaria is more dangerous to the fetus than treatment (particularly in a first pregnancy), some countries such as Malawi have adopted a policy of giving presumptive treatment to all women during their first pregnancy. In 1999 the 20th WHO Malaria Expert Committee recommended the following:

"*In view of the high maternal and infant morbidity and the mortality associated with malaria in pregnancy, intermittent treatment with an effective, preferably one-dose antimalarial drug delivered in the context of antenatal care should be made available to primi- and secundigravidae as an appropriate and effective method for reducing the consequences of malaria in pregnancy in highly endemic areas. Such intermittent treatment should be started from the second trimester onwards and not be given at intervals less than one month apart.*" [15]

This indicator is designed to measure the extent to which pregnant women attending antenatal clinics are offered malaria drugs as a prophylactic as described in the country's malaria policy. If giving prophylactics during pregnancy is not part of national policy then this indicator is not applicable.

Definition: Not all countries follow this regimen; some administer to all pregnant women while others do not have a policy on it. Where there is a policy, the drug of choice will probably be either chloroquine or SP. The recommended regimen for non-HIV-infected women is to give the dosage for an initial treatment of malaria during the second trimester of the pregnancy and then to repeat this practice during the third trimester. For women in areas with a high incidence of HIV infection, the regimen becomes monthly. Before including this indicator in the DMM assessment

[14] Chloroquine has been recommended as the drug of choice for prophylaxis during pregnancy by WHO and the U.S. Centers for Disease Control and Prevention (CDC) and, at normal doses, does not appear to pose any threat to the health of the fetus. Similarly, SP (Fansidar) used for malaria treatment at normal dosage levels has been shown to be safe during pregnancy. Although a theoretical concern, SP use in pregnancy has not been shown in practice to increase the incidence of kernicterus (a toxic degeneration of nerve cells) or other problems with newborns and has been used widely for treatment and prevention of malaria in pregnancy (typically used as intermittent therapy for prevention in Malawi).

See L.J. Schultz, R.W. Steketee, A. Macheso, et al. 1994. *American Journal of Tropical Medicine and Hygiene* 51(5): 515-522.

[15] Report of the 20th WHO Malaria Expert Committee, January 1999.

it will be necessary to clarify the country's policy with the national malaria program. **It can only be included if the particular country has a policy providing for giving prophylaxis to pregnant women.**

Data Collection:

Where to Go	Whom to Ask	What to Get
20 MOH health facilities	Medical Records Officer/Health Facility Manager/ Pharmacist	Identify a sample of 30 antenatal encounters per health facility and determine the number of prescribed antimalarials. Identify encounters either retrospectively by consulting daily registers, patient records, prescription slips, or prospectively through observation.

Encounters may need to be selected from pregnant women in the second and third trimesters. National guidelines should be consulted and followed on this point.

Before the study, organizers should decide which antimalarial is the appropriate one for the area where the survey takes place. Efforts should be made first to gather the data retrospectively from medical records. If the data are not available from records, then as an alternative, the data can be collected prospectively from observation. In many areas malaria is seasonal, which may limit the usefulness of the prospective data collection if the survey falls outside the malaria season. (See description of sampling methods in the Chapter 2 section, Selecting Data Collection Sites.)

All drugs prescribed should be transcribed on the data collection forms. Count the number of encounters prescribed an antimalarial.

See DUS-1B: Medical Records Review Form and DUS-2: Observation of Health Worker Data Form in the *Data Collector's Guide*.

Computation & Example: For each facility in a sample, the indicator is recorded as a percentage of the total number of antenatal encounters surveyed. The percentage is computed by dividing the number of antenatal encounters during which an antimalarial is prescribed for prophylaxis by the total number of antenatal encounters surveyed, and multiplying by 100. The overall indicator is the average of the facility-specific percentages. Along with this average, provide range figures.

$$\text{\% of Antenatal Encounters Prescribed an Appropriate Antimalarial} = \frac{\text{Total Number of Antenatal Encounters Prescribed Antimalarials}}{\text{Total Number of Antenatal Encounters Surveyed}} \times 100$$

- For example, results from one health facility are calculated as follows:

$$\text{\% of Antenatal Encounters Prescribed an Appropriate Antimalarial} = \frac{8}{24} \times 100 = 33\%$$

- If for 20 health facilities surveyed, data for a sample of 518 patient encounters showed that a total of 406 antenatal encounters received an appropriate antimalarial for treatment of malaria, then the average for all facilities would be—

$$\text{\% of Antenatal Encounters Prescribed an Appropriate Antimalarial for All Facilities} = \frac{406}{518} \times 100 = 78\%$$

Presentation: In a survey of 20 health facilities in country Z, an appropriate antimalarial was prescribed for prophylaxis during 78 percent of all antenatal encounters, with a range of 33 percent to 89 percent among facilities.

ANNEX 2. SAMPLE FORMAT FOR PRESENTING DMM INDICATOR DATA

Drug Availability Study Indicators

Indicator Name	Computation	Rationale	Results (Example Only)
1. Percentage of median international price paid for a set of DMM antimalarial drugs that was part of the last regular MOH procurement	(a) Individual drug: $\frac{\text{MOH Unit Price}}{\text{Median International Unit Price}} \times 100$ (b) All drugs: $\frac{\text{Sum of Percentages of All Antimalarial Drugs}}{\text{Total Number of Antimalarial Drugs}}$	To determine potential savings to the MOH that could be achieved with improved procurement practices	206.0%
2. Average percentage of a set of unexpired DMM antimalarial drugs available in (a) MOH storage and health facilities and (b) retail drug outlets	(a) Each Facility & Retail Drug Outlet: $\frac{\text{Number of Antimalarial Drugs with Unexpired Stock}}{\text{Total Number of Antimalarial Drugs Normally Stocked}} \times 100$ (b) All Facilities & Drug Retail Outlets: $\frac{\text{Sum of Average \% for Each Facility/Retail Outlet}}{\text{Total Number of Facilities/Outlets in Sample}}$	The successful implementation of a malaria drug policy is dependent on the drugs being available. If they are not, patients may not receive proper treatment.	48.0%
3. Average percentage of time out of stock for a set of DMM antimalarial drugs in MOH storage and health facilities	(a) Each drug: Record the Number of Days Out of Stock for Last 12 Months (b) All drugs: Sum Total Numbers of Days Out of Stock for Last 12 Months (c) $\frac{\text{Total Number of Stock-Out Days for All Antimalarial Drugs}}{365 \times \text{Total Number of Antimalarial Drugs Normally Stocked}} \times 100$	The successful implementation of a malaria drug policy is dependent on the drugs being available.	40.5%

Indicator Name	Computation	Rationale	Results (Example Only)
4. Average percentage of stock records that correspond with physical counts for a set of DMM antimalarial drugs in MOH storage and health facilities	(a) Each facility: Number of Stock Records with No Discrepancies x 100 Total Number of Records Examined (b) All facilities: Sum of Average % for Each Facility Total Number of Facilities in Sample	To monitor inventory control and identify problems such as theft, spoilage, poor record keeping, etc.	33.7%

Drug Use Study Indicators

Indicator Name	Computation	Rationale	Results (Example Only)
5. Percentage of MOH health facilities visited that had a copy of official treatment guidelines for malaria	Number of Facilities with Manual x 100 Number of Facilities in Sample	To measure the level of access to information to promote effective care and management of malaria based on national standard treatment guidelines.	45.0%
6. Percentage of encounters with patients diagnosed with uncomplicated malaria who are prescribed an antimalarial consistent with treatment guidelines	Total Number of Malaria Encounters Prescribed Appropriate Antimalarial x 100 Total Number of Malaria Encounters	To identify whether practitioners are complying with treatment guidelines	MOH: 78.4% (*n*=518) Drug Retail Outlet: 70.0% (*n*=20)

Indicator Name	Computation	Rationale	Results (Example Only)
7. Percentage of encounters with patients diagnosed with uncomplicated malaria who are prescribed quantities of appropriate antimalarials sufficient to complete a full course of treatment	(a) MOH Facilities Number of Malaria Prescriptions Sufficient for a Full Course / Number of Malaria Prescriptions x 100 (b) Drug Retail Outlets Number of Malaria Prescriptions Sufficient for a Full Course / Number of Malaria Prescriptions x 100	A key element of any strategy to slow the spread of resistance is that patients complete the full course of drug therapy prescribed for them. This indicator is to measure the extent to which the quantity of drugs prescribed is sufficient to complete a full course of treatment.	MOH: 84% Drug Retail Outlets: 65%
8. Percentage of prescribed antimalarial drugs actually dispensed by public health facilities	Total Number of Prescribed Drugs Actually Dispensed / Total Number of Prescribed Drugs Presented for Dispensing x 100	To measure the ability of the health facility to dispense prescribed drugs to patients/caregivers, i.e., the availability of appropriate drugs in health facilities	MOH: 74.0% (*n*=155)

Indicator Name	Computation	Rationale	Results (Example Only)
9. Percentage of cases where the quantity of antimalarial drugs dispensed by public health facilities was sufficient to complete a course of treatment	Number of Malaria Prescriptions Fully Dispensed / Number of Malaria Prescriptions Dispensed x 100	Problems of availability or cost often mean that patients leave a clinic with insufficient drugs to complete a full course of treatment. This indicator measures the extent to which public health facilities dispense a full course of treatment.	MOH: 85%
10. Average cost of drugs prescribed as a percentage of costs if STG norms for treatment were followed	(a) Total Cost of All Drugs Prescribed for Malaria Encounter / Total Cost of Drugs Recommended by STGs x 100 (b) Sum of % of Costs of All Facilities / Total Number of Facilities in Sample x 100	If it is assumed that malaria STGs represent the optimal cost, this indicator is useful to gain control over costs.	MOH: 335% Drug Outlet: 410%
11. Percentage of patients/caregivers who could correctly describe how to give the prescribed antimalarial medication	Total Number of Patients/Caregivers Who Correctly Describe How to Give Medication / Total Number of Patients/Caregivers Interviewed x 100	Patients/caregivers who do not know how to give the drug properly may not successfully treat themselves or their patient.	MOH: 52.1% (*n*=194)

Indicator Name	Computation	Rationale	Results (Example Only)
12. Percentage of health workers and drug retail outlets that provided some information to caregivers on how to give the recommended drug(s)	(a) Health Facilities: $\frac{\text{Total Number of Health Workers Providing Information}}{\text{Total Number of Encounters}} \times 100$ (b) Drug Retail Outlets: $\frac{\text{Total Number of Retail Outlets Providing Information}}{\text{Total Number of Encounters}} \times 100$	To determine whether malaria STGs are being followed by health care workers and monitor if health workers are providing enough information to patients.	MOH: 74.6% (*n*=245) Drug Outlet: 58.3% (*n*=60)

Supplemental Indicator

Indicator Name	Computation	Rationale	Results (Example Only)
13. Percentage of encounters with pregnant women living in endemic areas who are prescribed appropriate antimalarial prophylaxis at antenatal clinics	Total Number of Antenatal Encounters Prescribed Antimalarials / Total Number of Antenatal Encounters Surveyed x 100	This indicator is designed to measure the extent to which pregnant women attending antenatal clinics are offered malaria drugs consistent with STGs as a prophylactic as described in the country's malaria policy. If giving prophylactics during pregnancy is not part of national policy then this indicator is not applicable.	MOH: 35%

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